European Commission

Annual Activity Report 2025

annexes

Directorate-General for

Health and Food Safety

Contents

ANNEX 1: Statement of the Director(s) in charge of Risk Management and Internal Control

Director in charge of risk management and internal control

I declare that in accordance with the Commission's communication on the internal control framework ([1]), I have reported my advice and recommendations on the overall state of internal control in the DG to the Director-General.

I hereby certify that the information provided in section 2 of the present Annual Activity Report and in its annexes is, to the best of my knowledge, accurate and complete.

(e-signed)
Gabriella Fesus
Brussels,

Deputy Director-General for Health responsible for Directorates B to D

In DG SANTE's 2025 Annual Activity Report, Section 1, I have reported to the Director-General on the achievements of the operational objectives in the policy area Health.

I hereby certify that the information provided in Section 1 of the present Annual Activity Report and in its related annexes is, to the best of my knowledge, accurate and complete.

(e-signed)
Marco Marsella (acting)
Brussels,

Deputy Director-General for Food Sustainability responsible for Directorates E to G

In DG SANTE's 2025 Annual Activity Report, Section 1, I have reported to the Director-General on the achievements of the operational objectives in the policy area Food Safety.

I hereby certify that the information provided in Section 1 of the present Annual Activity Report and in its related annexes is, to the best of my knowledge, accurate and complete.

(e-signed)
Claire Bury

Brussels,

([1]) C(2017)2373 of 19.04.2017.

ANNEX 2: Performance tables

General objective 1: A new plan for Europe's sustainable prosperity and competitiveness

Specific Objective 1.1: Improve the competitiveness of the European health sector through innovation ([2])

Related to spending programme(s): EU4Health and others

Result indicator 1.1.1 Number of Commission Decisions adopted on human medicines authorisation (KPI)
Explanation: The number of decisions adopted based on the European Medicines Agency's assessments
Source of data: European Medicines Agency/DG SANTE
This result indicator is selected as a KPI

Baseline (2024)	Interim milestone (2027)	Target (2029)	Latest known results (situation on 31/12/2025)
100	Increase	Increase	112

Result indicator 1.1.2 Number of authorisations of clinical trials broken down by trial phase (I/II/III/IV)
Explanation: Indicator of the attractiveness of the EU as a destination for investment in medicine development, including notably the crucial "scale-up" phase, where there are fears of the EU falling behind its competitors.
Source of data: CTIS

Baseline (2024)	Interim milestone (2027)	Target (2029)	Latest known results (situation on 31/12/2025)
Phase I 585 Phase II 760 Phase III 613 Phase IV 275	614 798 643 288	644 836 674 302	496 801 652 268

([2]) This specific objective contributes also to General objective 3 Supporting people, and strengthening our societies and our social models

General objective 1: A new plan for Europe's sustainable prosperity and competitiveness

Specific Objective 1.1: Improve the competitiveness of the European health sector through innovation

Related to spending programme(s): EU4Health and others

Main outputs in 2025:

New policy initiatives

Output	Indicator	Target	Latest known results (situation on 31/12/2025)
Preparatory work for the proposal on a European Biotech Act	• Launch of studies in 2025 ((1) regulatory study (concerns food/feed as well as health), (2) landscape study, (3) rapid assessment study) • Public consultation • Call for evidence	Q2/Q3/Q4 2025	• Studies were launched with results expected in 2026. • Call for evidence and public consultation were closed in respectively June and November 2025.
Adopt Proposal for a European Biotech Act (proposal for a Regulation (COM/2025/1022 final) and proposal for a Directive (COM/2025/1031 final))	Adoption	Q4 2025	Adoption of the Commission proposal 16 December 2025

Initiatives linked to regulatory simplification and burden reduction

Output	Indicator	Target	Latest known results (situation on 31/12/2025)
Review of legislation on medical devices	Adoption	Q4 2025	Commission proposal for a targeted revision of the medical devices' regulations, adopted on 16 December 2025

Evaluations and fitness checks – part of the stress testing of the EU acquis			
Output	**Indicator**	**Target**	**Latest known results (situation on 31/12/2025)**
Evaluation on medical devices	Completion	Q4 2025	Evaluation completed as accompanying/supporting documents to the Commission proposal for revision of the legislation on 16 December 2025

Implementation dialogues, Annual Progress Report(s) and reality checks			
Output	**Indicator**	**Target**	**Latest known results (situation on 31/12/2025)**
Reality check(s) on medical devices	Meeting(s) held	Q1 2025	2 workshops held
2025 Annual Progress Report on Simplification, Implementation and Enforcement	Presentation to Health Ministers	Q4 2025	1 meeting of the Employment, Social Policy, Health and Consumer Affairs Council configuration (EPSCO) – 02/12/2025

Major public consultations			
Output	**Indicator**	**Target**	**Latest known results (situation on 31/12/2025)**
Public consultations on the evaluation and revision on medical devices	Consultations closed	Q1 2025	Consultations carried out for targeted evaluation and call for evidence carried out on the targeted revision

Major implementation activities and enforcement actions			
Output	**Indicator**	**Target**	**Latest known results (situation on 31/12/2025)**
Implementation Strategy for EHDS (future updates together with Article 102(4) EHDS Regulation progress report)	Adoption (note to be shared with Member States)	Q3 2025	Adoption postponed to Q2 2026. In 2025, priority was to provide support to Member States for the most time critical implementation activities. Implementation work is progressing according to the planning agreed with the EHDS Committee (see also below).

Other major outputs			
Output	**Indicator**	**Target**	**Latest known results (situation on 31/12/2025)**
Reform of the EU pharmaceutical legislation	Adoption by the co-legislators	In the course of 2025	Political agreement in December 2025
Study on challenges and barriers for the deployment of AI in healthcare	Publication of study	Q2 2025	Published in July 2025 https://op.europa.eu/en/publication-detail/-/publication/9ddf7bf8-62bf-11f0-bf4e-01aa75ed71a1/language-en#
Preparatory work for the implementation of the reform of the EU pharmaceutical legislation	Preparation of tertiary legislation	In the course of 2025	Mapping of required delegated and implementing acts to support preparation as of date of formal adoption in 2026
Revision of the guidelines on the variation system	Publication of the revised guidelines	Q3 2025	Published in September 2025 - OJ C, C/2025/5045, 22.9.2025
Revision of the pharmacovigilance implementing regulation	Publication of the revised guidelines	Q2 2025	Published in July 2025 - OJ L, 2025/1466, 23.7.2025

Output	Indicator	Target	Latest known results (situation on 31/12/2025)
Simplification of clinical trials implementation through harmonisation	Part of the Biotech Act	Q4 2025	Simplifications proposed in the amendment of the clinical trials Regulation as part of the European Biotech Act adopted on December 16 2025
Medical devices short-term actions	Adoption of implementing regulation and adoption of guidance	In the course of 2025	Implementing Regulation for uniform application of the requirements for notified bodies: public consultation on the draft text, ongoing 12 December 2025 - 23 January 2026 Implementing Regulation for reclassification of well-established technologies: abandoned Delegated Regulation for expansion of the list of well-established technologies: planned for adoption in Q1 2026 Adoption of a guidance for placement in the EU market of innovative breakthrough technologies
Implementation of the Regulation on the European Health Data Space (EHDS)	Acts adopted by the Commission	In the course of 2025	Following an agreement with the Member States in the EHDS Committee, the adoption of the key implementing acts is planned for 2026 and Q1 2027 (12 implementing acts planned to be adopted in total in this period).
Implementation of the Regulation on Health Technology Assessment	Number of joint clinical assessments (JCA) Number of joint scientific consultations HTA IT platform operational	Up to 25 Up to 10 Operational by Q1 2025	13 JCA launched 7 initiated, 4 completed, 1 withdrawn, 2 ongoing. Operational by Q1 2025 with continuous development ongoing

Output	Indicator	Target	Latest known results (situation on 31/12/2025)
Two implementing acts to be adopted under Health Technology Assessment Regulation	Adoption of implementing regulation on procedural rules for joint scientific consultations on medical devices and in vitro diagnostic medical devices Adoption of implementing regulation on procedural rules on joint clinical assessment of medical devices and Invitro diagnostic devices.	Q1 2025 Q3 2025	Commission Implementing Regulation (EU) 2025/117 of 24 January 2025 Commission Implementing Regulation (EU) 2025/2086 of 17 October 2025
Conference on EU HTA regulation	Meeting held	Q2 2025	2 July 2025 hybrid with over 200 onsite and 900 online participants.
Health Technology Assessment stakeholder network	Meetings held	Two meetings held in 2025	1 July and 24 October 2025
High-level event on Health Technology Assessment	Meetings held	In the course of 2025	Merged with conference above on 2 July
High-level event on medical devices	Meeting held	Q4 2025	Postponed to March 2026
High-level event on European Health Data Space	Meeting held	Q1 2025	Event took place 18/03/2025. Website: https://euhealthdataspace.eu/

General objective 1: A new plan for Europe's sustainable prosperity and competitiveness ([3])

Specific Objective 1.2: Resilient and effective health systems providing accessible and equitable healthcare

Related to spending programme(s): EU4Health and others

Result indicator 1.2.1 Self-reported unmet needs for medical examination due to financial reasons, long waiting lists or distance, as a percentage of the population reporting such needs.

Explanation: This indicator measures the ability of national health systems to ensure EU population receives the healthcare it needs. The impact of policies to reinforce national health systems should be partly captured by this indicator.

Source of data:

ec.europa.eu/eurostat/databrowser/view/hlth_silc_08b/default/table?lang=en&category=hlth.hlth_care.hlth_unm

This result indicator is selected as a KPI

Baseline (2022)	Interim milestone (2026)	Target (2029)	Latest known results (situation on 31/12/2024) ([4])
3.9% (ESTAT retroactive data update)	Decrease	Decrease	Reported at 3.6% for EU-27

Result indicator 1.2.2 Shortage of healthcare professionals.

Explanation: This indicator measures the impact of efforts made at national and EU level to strengthen healthcare workforce to address EU population needs.

Source of data: OECD

Baseline (2022)	Interim milestone (2026)	Target (2029)	Latest known results (situation on 31/12/2025)
1.2 million	Decrease	Decrease	Based on Eurostat data available for reporting Member States (n=20) the number of physicians, midwives and nurses combined increased with 1.1% between 2022 and 2023 ([5]).

([3]) This specific objective contributes also to General objective 3 Supporting people, and strengthening our societies and our social models.

([4]) From 2024 on, the indicator is reported for all 27 Member States. The 2025 update is scheduled for end-April 2026.

([5]) OECD and Eurostat use slightly different definitions. However, the OECD number will be updated with the "Health at a Glance 2026 edition".

Result indicator 1.2.3 Number of shortages of medicines in the single point of contact (SPOC) network reported by Member States

Explanation: This indicator measures the level of monitoring and reporting on relevant shortages of human and veterinary medicines by measuring the number of shortages of medicines that were identified as critical with respect to their impact on human/animal health, as reported by the Member States to the SPOC Working Party. The indicator is a relative proxy indicator which does not necessarily correlate with the number of critical shortages at EU level, given that an increase in reported shortages can either be due to an increase in the number of actual shortages or due to better reporting and monitoring by Marketing Authorisation Holders and Member States. The values for this indicator may increase in the short term due to a increased level of reporting and monitoring and is expected to stagnate once the forthcoming Pharmaceutical package starts to take effect.

Source of data: European Medicines Agency

Baseline (2024)	**Interim milestone (2026)**	**Target (2029)**	**Latest known results (situation on 31/12/2025)**
69	110	90	58

Result indicator 1.2.4 Number of Member States connected to MyHealth@EU and HealthData@EU ([6]) digital cross-border infrastructures

Explanation: This indicator measures the progress made towards the implementation of the European Health Data Space (EHDS), through setting up the central services for the two digital infrastructures by the Commission and connections to the two digital infrastructures by the Member States.

Source of data: Reporting obligations under the EHDS Regulation

Baseline (2024)	**Interim milestone (2027)**	**Target (2029)**	**Latest known results (situation on 31/12/2025)**
MyHealth@EU: 15 HealthData@EU: n/a	MyHealth@EU: 20 HealthData@EU: n/a	MyHealth@EU: 27 HealthData@EU:27	MyHealth@EU: 16 HealthData@EU: n/a

([6]) The HealthData@EU infrastructure will be operational only as of 2029.

General objective 1: A new plan for Europe's sustainable prosperity and competitiveness

Specific Objective 1.2: Resilient and effective health systems providing accessible and equitable healthcare

Related to spending programme(s): EU4Health and others

Main outputs in 2025:

New policy initiatives

Output	Indicator	Target	Latest known results (situation on 31/12/2025)
Proposal on a Critical Medicines Act	Adoption by the Commission	Adoption date: 11/03/2025	Interinstitutional process advancing: Council position on 02/12/25 and EP position on 20/01/26
Staff Working Document on the proposal for a Critical Medicines Act	Publication	June 2025	Published

Evaluations and fitness checks – part of the stress testing of the EU acquis

Output	Indicator	Target	Latest known results (situation on 31/12/2025)
Report on the interim evaluation of the EU4Health Programme and accompanying staff working document	Completion	Completed in 2025	Completed

Other major outputs

Output	Indicator	Target	Latest known results (situation on 31/12/2025)
Adoption of the 2025 EU4Health work programme	Adoption by the Commission	In the course of 2025	Adopted on 23 July 2025
2024 EU4Health Programme Performance Statement	Adoption by the Commission	In the course of 2025	Adopted on 19 June 2025

Output	Indicator	Target	Latest known results (situation on 31/12/2025)
Negotiations with third countries for association to the EU4Health programme	Successful association of third countries to the EU4Health programme	In the course of 2025	Association of Serbia (signed by the Commission on 8 December 2025)
New tools to inform policies on access to healthcare (EU4Health actions)	Methodology to assess the impact of in-kind health benefits on poverty and income inequalities developed Guidelines for Member States on improving access to healthcare for persons with disabilities developed and 3 workshops on implementation organised	Q2 2025 Q3 2025	Completed Completed
Training of health professionals with a focus on digital skills (EU4Health action)	At least 20 thousand health professionals trained	Q4 2025	Completed
Seminar for Member States on the use of health workforce planning in reforms of health systems (EU4Health action)	International seminar for Member States	Q3 2025	Completed (Conference in Malta, 26-29 October 2025)
Reports and workshops by Health Systems Performance Assessment Expert Group	Report on "low-value care" published and workshop held on health workforce	Q1-Q3	Report published on 13/02/2025 Workshop held on 16/10/2025
State of Health in the EU, 5th cycle Country health profiles and synthesis report	29 country profiles and synthesis report published	Q4 2025	Done (published on 11 December 2025)
High-level event on cross-border healthcare Directive and European Reference Networks (ERNs)	Meeting held	Q4 2025	Meeting postponed to Q1 2026 4 national workshops co-organised with MSs were held in 2025

Output	Indicator	Target	Latest known results (situation on 31/12/2025)
Implementation of the new SoHO Regulation	Adoption of the implementing act setting up the SoHO platform Set up of the SoHO coordination board and its six working groups	Q3 2025 Q2 2025	Commission implementing Regulation (EU) 2025/1467 on the EU SoHO platform was published in the OJ on 21 July 2025 SoHo coordination group and 6 sub-groups set-up

General objective 2: A new era for European defence and security

Specific Objective 2.1: Strengthened health security, through preparedness for, prevention of and response to serious cross-border threats to health

Related to spending programme(s): EU4Health and others

Result indicator 2.1.1 Number of countries having developed or updated a national preparedness action plan following recommendations from the Public Health Emergency Preparedness Assessments (PHEPA mission) ([7])

Explanation: The indicator measures the progress in prevention, preparedness and response to serious health events by counting the number of EU/EEA countries with a new or updated national plan integrating the recommendations of the PHEPA missions.

Unit of measurement: cumulative number of countries

Source of data: Member States

This result indicator is selected as a KPI

Baseline (2024)	Interim milestone (2027)	Target (2029)	Latest known results (situation on 31/12/2025)
0	20	30	4

([7]) As stated in the Regulation (EU) 2022/2371 on Serious Cross-Border Threats to Health, the European Centre for Disease prevention and Control (ECDC) in coordination with relevant Union agencies and bodies, conduct Public Health Emergency Preparedness Assessments (PHEPA) of all 30 European Union and European Economic Area (EU/EEA) countries every three years to assess the state of implementation of their national prevention, preparedness and response planning.

Result indicator 2.1.2: Number of European Reference Laboratories (EURLs) for Public Health in operation **Explanation:** The indicator measures the progress in Public Health laboratory capacity at EU level for priority infectious diseases and other health events by monitoring the number of EURLs. Unit of measurement: cumulative number of EURLs **Source of data:** DG SANTE			
Baseline (2024)	**Interim milestone (2027)**	**Target (2029)**	**Latest known results (situation on 31/12/2025)**
6	11	14	10

Result indicator 2.1.3 Updated Union prevention, preparedness and response plan for health crisis **Explanation:** The indicator measures the capacity to adapt the Union prevention, preparedness and response plan through monitoring the updates of the plan that incorporate the recommendations of the regular test exercises. **Source of data:** DG SANTE			
Baseline (2025)	**Interim milestone (2027)**	**Target (2029)**	**Latest known results (situation on 31/12/2025)**
First version of the Union plan	Union plan is up-to-date and fit-for-purpose considering possible changes in the EU policy and legal framework and based on lessons learned from real-life events and/or the two simulation exercises organised in 2026 and 2027	Union plan is up-to-date and fit-for-purpose considering changes in the EU policy and legal framework and based on lessons learned from real-life events and/or the three simulation exercises organised in 2026–2028	The Union prevention, preparedness and response plan for health crises was adopted on 28 November 2025. The organisation of the first simulation exercise to test the Union plan in June 2026 is on-going.

General objective 2: A new era for European defence and security

Specific Objective 2.1: Strengthened health security, through preparedness for, prevention of and response to serious cross-border threats to health

Related to spending programme(s): EU4Health and others

Main outputs in 2025:

Evaluations and fitness checks – part of the stress testing of the EU acquis

Output	Indicator	Target	Latest known results (situation on 31/12/2025)
Evaluation of the legislation on cross-border health threats	Publication	Q3 2025	Postponed to Q1 2026

Other major outputs

Output	Indicator	Target	Latest known results (situation on 31/12/2025)
Union prevention, preparedness and response plan for health crises	Adoption by the Commission	Q4 2025	Adopted on 28 November 2025 The organisation of the first simulation exercise to test the Union plan in June 2026 is on-going.
Legal act establishing a new European Union Reference Laboratory for respiratory viruses	Adoption by the Commission	Q4 2025	Adopted on 16 December 2025

Output	Indicator	Target	Latest known results (situation on 31/12/2025)
Implementing/delegated acts on: - surveillance and the requisite digital platform - the EU Health Task Force response coordination in the Health Security Committee	Adoption by the Commission	Q4 2025	Four delegated and implementing acts on surveillance expected to be adopted in Q3/ 2026 and the last one in 2028. ([8]) The implementing act on EU Health Task Force was adopted in July 2025. The implementing act on coordination in the HSC should be adopted in Q1 2026.

General objective 2: A new era for European defence and security

Specific Objective 2.2: Implementing a One Health approach

Related to spending programme(s): EU4Health and others

Result indicator 2.2.1 Consumption of antibiotics in humans

Explanation: The total consumption of antibiotics in humans (in Defined Daily Dose (DDD) per 1,000 inhabitants per day), in the community and hospital sectors combined, including in long-term care facilities and in home-care settings.

Source of data: ECDC https://www.ecdc.europa.eu/assets/amr-targets-2024/index.html

This result indicator is selected as a KPI

Baseline (2019)	Interim milestone (2027)	Target (2030) ([9])	Latest known results (situation on 31/12/2025)
19.9 DDD	Decrease	15.9 DDD (20% reduction):	20.3 DDD ([10])

([8]) Due to complexity and extensive necessary consultations with relevant experts.

([9]) 2030 is the target year stated in the Council Recommendation on stepping up EU actions to combat antimicrobial resistance in a One Health approach 2023/C 220/01.

([10]) The 2024 data indicate a slight increase, which may be associated with the continued inappropriate use of antibiotics and suboptimal infection prevention and control practices. It should be noted that the 2024 data were collected prior to the adoption of key policy measures, including the UNGA Political Declaration on AMR and the Health Security Committee's opinion on carbapenem-resistant Enterobacterales.

Result indicator 2.2.2 Increase in percentage of the areas officially free from certain zoonoses (Bovine Brucellosis, Sheep and Goat Brucellosis, Tuberculosis)

Explanation: Member States implement eradication programmes to eliminate certain zoonoses from their territories (infection with Mycobacterium tuberculosis complex – M. b*ovis, M. caprae* and *M. tuberculosis* – and with *Brucella abortus, B melitensis* and *B.suis*). The indicator measures the progress achieved in eradication. Unit: increase in percentage of areas officially free from these zoonoses.

Source of data: DG SANTE

Baseline (2025)	**Interim milestone (2027)**	**Target (2029)**	**Latest known results (situation on 31/12/2025)**
25%	28%	30%	40%

Result indicator 2.2.3 Sales of antimicrobials in farmed animals and aquaculture

Explanation: This indicator measures the overall EU sales of veterinary antimicrobials for farmed animals and aquaculture. The measurement unit is mg/PCU i.e. mg of active substance sold per population correction unit (PCU). The PCU is applied as a proxy for the size of the food-producing animal population and serves to normalise the sales data by the number of animals that could be potentially treated with antimicrobials.

Source of data: ESVAC (until reporting year 2022) and ESUAvet (as of reporting year 2023) annual reports. Latest ESUAVet report, with date for 2024 here: **https://www.ema.europa.eu/en/documents/report/european-sales-use-antimicrobials-veterinary-medicine-annual-surveillance-report-2023_en.pdf** European sales and use of antimicrobials for veterinary medicine - Annual surveillance report for 2024

Baseline (2018) ([11])	**Interim milestone (2027)**	**Target (2030) ([12])**	**Latest known results (situation on 31/12/2024) ([13])**
118.3 mg/PCU	Decrease	59.3mg/PCU	89.6 mg/PCU The latest available data are for 2024 (published in December 2025)

([11]) The baseline is based on data for 2018, included in the tenth ESVAC report which was published in 2020.

([12]) 2030 is the target year set in the Farm to Fork strategy. Data for 2030 will be available in December 2031.

([13]) The aspirational target, set in the Farm to Fork Strategy, is to reduce overall EU sales of antimicrobials for farmed animals and in aquaculture by 50% by 2030, comparing to overall EU sales in 2018.

General objective 2: A new era for European defence and security

Specific Objective 2.2: Implementing a One Health approach

Related to spending programme(s): EU4Health and others

Main outputs in 2025:

Other major outputs

Output	Indicator	Target	Latest known results (situation on 31/12/2025)
Feasibility study on integrated surveillance systems on antimicrobial resistance and antimicrobial consumption encompassing human health, animal health, plant health, food, wastewater and the environment, under Council Recommendation on stepping up EU actions to combat antimicrobial resistance in a One Health approach	Publication of final report	Q3 2025	Study published on 13 November 2025: https://health.ec.europa.eu/publications/feasibility-study-integrated-surveillance-systems-amr-and-amc-encompassing-human-health-animal_en
Meeting of the EU AMR One Health network with Member States	Meeting held	Q4 2025	Two meetings of the EU AMR One Health Network were held on 3-4 April 2025 and 24-25 November 2025 with approximately 130 participants.

Output	Indicator	Target	Latest known results (situation on 31/12/2025)
One Health thematic network on the Health Policy Platform	Launch	Q3/4 2025	The kick-off meeting took place on 24 November and the first public pitch webinar took place on 4 December (76 participants joined the first webinar, showing a high interest rate for the new cycle of Thematic Networks) The One Health Thematic Network is led by the European One Health Association. Around 50 organisations/members have already joined the One Health Network, representing different countries, stakeholders and sectors. https://health.ec.europa.eu/events/2025-thematic-networks-pitch-webinar-meet-leaders-learn-about-their-proposals-2025-12-04_en
Amendment of Implementing Regulation (EU) 2024/1973 to extend its scope to animals of the equine species and set out conditions for the use of certain antimicrobials in these animals in accordance with Articles 112 and 113 of Regulation (EU) 2019/6	Preparatory work	In the course of 2025	Work in progress

Output	Indicator	Target	Latest known results (situation on 31/12/2025)
Amendment of Commission Implementing Regulation (EU) 2024/2598 laying down the list of third countries or regions thereof authorised for the entry into the Union of certain animals and products of animal origin intended for human consumption in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council as regards the application of the prohibition on the use of certain antimicrobial medicinal products	Preparatory work	In the course of 2025	Work in progress

General objective 3 Supporting people, and strengthening our societies and our social models

Specific Objective 3.1: Improving people's health by reducing the burden of non-communicable diseases

Related to spending programme(s): EU4Health and others

Result indicator 3.1.1 Number of Member States which have achieved breast, cervical and colorectal cancer screening examinations at the level of the benchmarks

Explanation: This indicator measures the number of Member States which have achieved breast cancer screening coverage of over 70%, cervical cancer screening examination coverage of 70% and colorectal cancer screening examination coverage of 45%. These benchmarks are defined in line with European guidelines and quality assurance schemes, as proposed by the EU4Health-funded project CanScreen-ECIS. EU cancer screening schemes are a flagship initiative of Europe's Beating Cancer Plan.

Source of data: This indicator is calculated based on Eurostat Preventive cancer screenings - programme data.
https://ec.europa.eu/eurostat/databrowser/view/hlth_ps_prev/default/table?lang=en

This result indicator is selected as a KPI

Baseline (2022)	**Interim milestone (2027)**	**Target (2029)**	**Latest known results (situation on 31/12/2023)**
3	Increase	Increase	4 (latest available data is from 2023)

Result indicator 3.1.2 Prevalence of use of tobacco and nicotine products

Explanation: The indicator measures the EU average of the share of the population aged 15 years and over who reported current use of any tobacco and nicotine products.

Source of data:
https://ec.europa.eu/eurostat/databrowser/view/sdg_03_30/default/table The data are collected through a Eurobarometer survey and are based on self-reports during face-to-face interviews in people's homes.

Baseline (2023)	**Interim milestone (2026)**	**Target (2029)**	**Latest known results (situation on 31/12/2025)**
26.5%	Decrease	Decrease	No update (next Eurobarometer expected for 2026)

Result indicator 3.1.3 Number of EU Member States having reached at least 90 % coverage for a full Human papillomavirus virus (HPV) vaccination course (last dose) in eligible girls **Explanation:** The indicator measures the progress towards fully vaccinating 90% of girls against HPV at EU level in line with the objective in Europe's Beating Cancer Plan and the Council Recommendation on vaccine-preventable cancers (C/2024/4259) which set out that all Member States should achieve this target by 2030. Unit: Cumulative number of EU Member States **Source of data:** WHO immunisation data portal			
Baseline (2024) ([14])	**Interim milestone (2027)**	**Target (2030)**	**Latest known results (situation on 31/12/2025)**
1	10	27	1
Result indicator 3.1.4 Health budget for prevention **Explanation:** This indicator measures the share of preventive care spending as part of total health spending (average in EU countries). **Source of data:** OECD Data Explorer • Health expenditure and financing			
Baseline (2022)	**Interim milestone (2026)**	**Target (2029)**	**Latest known results (situation on 31/12/2025)**
4.2%	Increase	Increase	4.0%

([14]) As of 31 December 2025, three EU/EEA countries Iceland, Norway and Portugal reached 90% of coverage for HPV vaccination coverage by the age of 15 (WHO indicator), based on the data from 2024 (published in August 2025). These three countries have consistently reached 90% since 2021 and up to 2024 estimates. Consequently, there was only one EU country meeting this 90% target. The original baseline for 2024 was erroneously set at 2, which has since been corrected to 1.

General objective 3: Supporting people, and strengthening our societies and our social models

Specific Objective 3.1: Improving people's health by reducing the burden of non-communicable diseases

Related to spending programme(s): EU4Health and others

Main outputs in 2025:

New policy initiatives

Output	Indicator	Target	Latest known results (situation on 31/12/2025)
EU cardiovascular health plan	Adoption by the Commission	Q4 2025	Adopted on 16 December 2025
Proposal for a Council Recommendation on the limitation of exposure of the general public to electromagnetic fields	Adoption by the Commission	Q3/Q4 2025	Initiative abandoned

Evaluations and fitness checks – part of the stress testing of the EU acquis

Output	Indicator	Target	Latest known results (situation on 31/12/2025)
Evaluation of the Tobacco Products Directive and the Tobacco Advertising Directive	Preparatory work	Q4 2025 / Q1 2026	Ongoing (expected for Q1 2026)

Major public consultations

Output	Indicator	Target	Latest known results (situation on 31/12/2025)
Public consultation on Cardiovascular Health Plan	Launch of the public consultation	Q3/Q4 2025	Call for Evidence with 677 contributions (11 August- 17 September 2025)
EU-wide inquiry on mental health and social media	Preparatory work	In the course of 2025	Ongoing

Other major outputs			
Output	**Indicator**	**Target**	
Youth Policy Dialogue on cancer	Delivery	Q1 2025	https://health.ec.europa.eu/events/youth-policy-dialogue-commissioner-oliver-varhelyi-cancer-2025-02-04_en
Launch of the EU Network of Comprehensive Cancer Centres	Delivery	Q4 2025	Launched on 7 November 2025 (https://eunetccc2025.eu/)

General objective 4 Sustaining our quality of life: food security, water and nature
Specific Objective 4.1 Contributing to the competitiveness of the food sector and ensuring food and feed safety

Related to spending programme(s): Single Market Programme

Result indicator 4.1.1 The percentage of legislative and implementing initiatives delivered as planned

Explanation: This indicator will measure the accuracy in planning and implementation of SANTE Management plan, counting the number of initiatives delivered according to the annual management plan. Realistic timelines that take account of all possible delays in preparing, adopting and implementing initiatives, reduce uncertainty and provide a reliable business climate, contributing to EU competitiveness.

Source of data: DG SANTE calculation.

This result indicator is selected as a KPI

Baseline average 2021-24	**Interim milestone 2027**	**Target 2029**	**Latest known results (situation on 31/12/2025)**
68%	70%	75%	70%

Result indicator 4.1.2. Number of phytosanitary programmes successfully implemented / total number of phytosanitary programmes approved

Explanation: It measures the level of implementation of approved programmes in compliance with EU SPS laws.

Source of data: HADEA

Baseline (2023)	**Interim milestone (2027)**	**Target (2029)**	**Latest known results (situation on 31/12/2025)**
100%	100%	100%	100%

Result indicator 4.1.3. Relative proportion of Commission controls undertaken in third countries with respect to Commission controls undertaken in Member States.
Explanation: By monitoring how the Commission divides its audit resources between third countries and Member States, the indicator provides an objective perspective on how the commitment is being translated into practice to further strengthen the control on food and feed imports into the EU.
Source of data: DG SANTE, published HFFA work programme

Baseline (2024)	Interim milestone (2027)	Target (2029)	Latest known results (situation on 31/12/2025)
38%	42%	46%	35%

Result indicator 4.1.4. Use and risk of chemical pesticides
Explanation: Monitoring UN SDG 2 in an EU context involves tracking progress towards sustainable agricultural practices and reducing the use and risk of chemical pesticides. The indicator is used to monitor progress towards the non-legally binding target of a 50% reduction by 2030. The market withdrawal of more hazardous pesticides may lead to the use of higher amounts of lower risk pesticides. This means that the trajectory towards the target is unlikely to be linear, with some fluctuations above and below the trendline expected.
Source of data: DG SANTE (Eurostat online data code: sdg_02_53)

Baseline (2015-17)	Interim milestone (2026)	Target (2030)	Latest known results (situation on 31/12/2025)
100	48	50	42 (relates to latest available data covering year 2023)

Result indicator 4.1.5. Food waste

Explanation: The fight against food waste is closely linked with the UN Sustainable Development Goal (SDG Target 12.3) to halve per capita global food waste at retail and consumer levels by 2030.

The EU plays a key role in accelerating and scaling up efforts to reduce food waste. Member States are required to reduce food waste at each stage of the food supply chain, monitor food waste levels and report on progress. In addition, the recent amendment of the Waste Framework Directive (Directive (EU) 2025/1892), established mandatory reduction targets in Member States by 2030 (by 10% in processing and manufacturing, and 30% (per capita) at retail and consumption (restaurants, food services, and households)).

Source of data: Eurostat

Baseline (2020)	**Interim milestone (2026)**	**Target (2029)**	**Latest known results (situation on 31/12/2023) ([15])**
59.2 million tons	56.2 million tons (data from 2024) or 5% reduction ([16])	50.3 million tons (data from 2027) or 15% reduction ([17])	58.2 million tons

([15]) The time lag for reporting data originates from legislation specifics, particularly Article 37(3) of the Directive 2008/98/EC on waste. Member States are required to report data annually, with submission due 18 months after the end of the reporting year.

([16]) Own assessment, based on expected Member States performance

([17]) Own assessment, based on expected Member States performance. May be subject to change depending on date of entry into force of food waste reduction targets.

General objective 4: Sustaining our quality of life: food security, water and nature

Specific Objective 4.1: Contributing to the competitiveness of the food sector and ensuring food and feed safety

Related to spending programme(s): Single Market Programme

Main outputs in 2025:

New policy initiatives

Output	Indicator	Target	Latest known results (situation on 31/12/2025)
Proposal for a Regulation to tackle the illegal placing on the market, as fresh, of tuna frozen in brine destined to canning	Adoption by the Commission	Q3 2025	Adopted on 18/07/2025

Initiatives linked to regulatory simplification and burden reduction

Output	Indicator	Target	Latest known results (situation on 31/12/2025)
Proposal for a Food and Feed Safety Simplification Omnibus	Adoption by the Commission	Q4 2025	Adopted on 16/12/2025

Evaluations and fitness checks – part of the stress testing of the EU acquis

Output	Indicator	Target	Latest known results (situation on 31/12/2025)
Evaluation of the Biocidal Products Regulation (EU) No 528/2012	Initial analysis of Member States' Implementation Reports Start of the work under the contract for a study in support of the evaluation Work on the evaluation	Q3 2025 Q4 2025 Ongoing activity	Terms of reference of the study under finalisation, awaiting publication. Call for evidence published on 11 Decembre 2025
External study to support the Commission's evaluation of EFSA's Performance	Completion of external study	Q2 2025	Completed (Q4 2025)

Implementation dialogues, Annual Progress Report(s) and reality checks			
Output	**Indicator**	**Target**	**Latest known results (situation on 31/12/2025)**
Implementation Dialogue on the Biocidal Products Regulation (Regulation (EU) No 528/2012)	Meeting held	Q3 2025	Meeting held. Some findings are taken into account in the Food and feed safety simplification package; other elements will be considered in the evaluation of the Biocidal Products Regulation.
Implementation Dialogue on import controls	Meeting held	December 2025	Meeting held on 09/12/2025
2025 Annual Progress Report on Simplification, Implementation and Enforcement	Presentation to the Ministers of Agriculture	Q4 2025	1 meeting of the Agriculture and Fisheries Council configuration (AGRIFISH) – 17/11/2026
Major public consultations			
Output	**Indicator**	**Target**	**Latest known results (situation on 31/12/2025)**
Public consultation in the context of the evaluation on plant variety legislation and founding legislation of the CPVO	Launch of the public consultation	Q4 2025	Postponed

Major implementation activities and enforcement actions			
Output	**Indicator**	**Target**	**Latest known results (situation on 31/12/2025)**
Implementation strategy for the Commission's proposal on plants obtained by certain new genomic techniques (COM(2023) 411 final)	Adoption	Q4 2025	Preparatory work on-going based on provisional political agreement of 3 December 2025.

Other major outputs			
Output	**Indicator**	**Target**	**Latest known results (situation on 31/12/2025)**
Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Directive 2008/98/EC on waste (food waste part of the Waste Framework Directive)	Agreement by the co-legislators	Q1 2025	Directive adopted. (Directive (EU) 2025/1892 of the European Parliament and of the Council of 10 September 2025 amending Directive 2008/98/EC on waste)
Priority pending proposals ([18]) Proposal for a REGULATION on plants obtained by certain new genomic techniques and their food and feed, and amending Regulation (EU) 2017/625 Proposal for a REGULATION on the production and marketing of forest reproductive material, amending Regulations (EU) 2016/2031 and 2017/625 and repealing Council Directive 1999/105/EC (Regulation on forest reproductive material) Proposal for a REGULATION on the production and marketing of plant reproductive material in the Union (Regulation on plant reproductive material)	Progress/agreement by the co-legislators	In the course of 2025	Provisional political agreement reached by the co-legislators on 3 December 2025. Political agreement reached on 10 December 2025.

([18]) The list includes proposals led by DG SANTE that were announced as priority proposals in annex III
of the 2025 Commission Work Programme and that were pending agreement by the co-legislators at end 2024

Output	Indicator	Target	Latest known results (situation on 31/12/2025)
Implementation of the legal frameworks for various groups of substances used for the production of foods, novel foods, GMOs and derived products (authorisation, prohibition, limits, use conditions, labelling, etc) and other uses	Adoption of relevant decisions	Ongoing regular activity in 2025	Regular activity
Legal acts related to the control of residues of veterinary medicinal products	Adoption	Ongoing regular activity in 2025	Regular activity
Implementation of the legal frameworks for plant protection products and biocidal products (e.g. decisions on approvals, renewal of approvals, authorisations, postponement of expiry dates, limits for residues in food, etc.)	Adoption	Ongoing regular activity in 2025	For biocides: 126 decisions adopted, related to the approval of active substances, the Union authorisation of biocidal products, on disagreements between Member States during mutual recognition procedures, and on national derogations for Member States » For pesticides: 26 Regulations adopted, related to approval or renewal of approval of active substances, to adaptation of conditions of approval, to extensions of approval periods and to implementation of Reg (EC) No 1107/2009 - For pesticides residues: 11 Regulations adopted setting or amending maximum residue levels
Commission report regarding Member States' experience with the contained use of genetically modified microorganisms in the 2022-2024 period	Adoption	Q4 2025	ISC completed and translations on-going. Planned adoption Q1 2026.
Implementation of the legal frameworks on food contact materials and processes of recycling plastics	Adoption	Ongoing regular activity in 2025	Regular activity

Output	Indicator	Target	Latest known results (situation on 31/12/2025)
Authorisation of veterinary medicinal products following EMA opinions	Adoption	Ongoing regular activity in 2025	30 new marketing authorisations granted
Setting maximum residue limits for veterinary medicinal products following EMA opinions	Adoption	Ongoing regular activity in 2025	3 acts adopted: - **Commission Implementing Regulation (EU) 2025/1908** http://data.europa.eu/eli/reg_impl/2025/1908/oj - **Commission Implementing Regulation (EU) 2025/1105** http://data.europa.eu/eli/reg_impl/2025/1105/oj - **Commission Implementing Regulation (EU) 2025/1102** http://data.europa.eu/eli/reg_impl/2025/1102/oj
Setting or updating limits for contaminants in feed and food following EFSA opinions	Adoption	Ongoing regular activity in 2025	Regular activity
Implementation of the harmonised food safety acquis in the areas of food and feed safety, animal health and welfare, animal breeding, animal by-products, plant health, plant reproductive material, plant variety rights, plant genetic resources and official controls.	Adoption	Ongoing regular activity in 2025	Regular activity

Output	Indicator	Target	Latest known results (situation on 31/12/2025)
Legal acts related to veterinary medicinal products	9 Adoptions + preparatory work	Ongoing regular activity in 2025	- 7 acts Adopted:**C/2025/526** http://data.europa.eu/eli/C/2025/663/oj - **Commission Implementing Regulation (EU) 2025/1103** http://data.europa.eu/eli/reg_impl/2025/1103/oj - **Commission Implementing Regulation (EU) 2025/2091** http://data.europa.eu/eli/reg_impl/2025/2091/oj - **Commission Implementing Regulation (EU) 2025/2154** http://data.europa.eu/eli/reg_impl/2025/2154/oj - **Commission Regulation (EU) 2025/1101** http://data.europa.eu/eli/reg/2025/1101/oj - **Commission Implementing Regulation (EU) 2025/901** http://data.europa.eu/eli/reg_impl/2025/901/oj - **Commission Implementing Regulation (EU) 2025/163** https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:L_202500163 + preparatory work on 4 acts

Output	Indicator	Target	Latest known results (situation on 31/12/2025)
REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL on the Commission assessment of the situation as regards the treatment with medicinal products of animals of the equine species and their exclusion from the food chain, including with regard to imports of animals of the equine species from third countries	Adoption	In the course of 2025	Adopted **COM/2025/699 final** https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52025DC0699&qid=1766417468193
Report from the Commission to the European Parliament and the Council on traditional herbal products used to treat animals in the Union	Preparatory work	In the course of 2025	Work in progress
Call for evidence for a proposal for a Regulation on the setting of maximum and minimum amounts of vitamins and minerals in food supplements and fortified foods in the European Union	Launch of call for evidence Publication on summary report	Q2 2025 Q4 2025	Postponed
Audits on the implementation of the sustainable use directive (SUD)	Inclusion in the HFAA annual work programme	Q4 2025	Included in the HFAA
Authorisation of medicinal products for human use following EMA opinions	Adoption	Ongoing regular activity in 2025	112 new marketing authorisations granted

General objective 4 Sustaining our quality of life: food security, water and nature
Specific Objective 4.2: Modernising animal welfare based on latest scientific evidence and strengthening the single market
Related to spending programme(s): Single Market Programme

Result indicator 4.2.1. Number of animal welfare notifications per year under the iRASFF Animal Welfare Module
Explanation: This measure demonstrates the cooperation of Member States in enforcing animal welfare legislation (iRASFF).
Source of data: DG SANTE (iRASFF)
This result indicator is selected as a KPI

Baseline (2024)	Interim milestone (2027)	Target (2029)	Latest known results (situation on 31/12/2025)
0	150	200	929 notifications in 2025

Result indicator 4.2.2. Number of persons that followed EU trainings on animal welfare (BTSF workshops, BTSF online trainings, STM)
Explanation: This measure indicates the dissemination of knowledge of EU animal welfare rules, notably to government officials, who are responsible for spreading knowledge and best practices in their respective countries.
Source of data: DG SANTE

Baseline (2024)	Interim milestone (2027)	Target (2029)	Latest known results (situation on 31/12/2025)
655	750	800	757

General objective 4: Sustaining our quality of life: food security, water and nature

Specific Objective 4.2: Modernising animal welfare based on latest scientific evidence and strengthening the single market

Related to spending programme(s): Single Market Programme

Main outputs in 2025:

Major public consultations

Output	Indicator	Target	Latest known results (situation on 31/12/2025)
Public consultation in view of an upcoming legislative proposal on on-farm welfare (expected in 2026)	Launch	Q3 2025	Launched in Q3 2025

Other major outputs

Output	Indicator	Target	Latest known results (situation on 31/12/2025)
In view of an upcoming legislative proposal on on-farm welfare (expected in 2026): • 3 meetings of the Platform on Animal Welfare • Call for evidence • Study supporting the impact assessment	Events organised Publication Launch	Q1, Q2 and Q4 2025 Q2 2025 Q3 2025	3 meetings of the Platform on Animal Welfare took place (Q1, Q2 and Q4 2025) The Call for evidence was published in June 2025. The study supporting the impact assessment was launched in Q3 2025.

Output	Indicator	Target	Latest known results (situation on 31/12/2025)
Priority pending proposals ([19]) - Proposal for a Regulation on the protection of animals during transport and related operations, amending Council Regulation (EC) No 1255/97 and repealing Council Regulation (EC) No 1/2005 - Proposal for a Regulation on the welfare of dogs and cats and their traceability	Progress/agreement by the co-legislators	For transport – advancing the negotiations with co-legislators in 2025 For the welfare of dogs and cats: finalisation of the trilogues by the end of 2025	Regulation on the protection of animals during transport: negotiations have progressed in Council. Regulation on the welfare of dogs and cats and their traceability: trilogues have concluded positively on 25 November 2025
Overview report on the long transport of young calves	Publication	Q2 2025	Published in Q2 2025
Preparatory work for the Commission Communication to be adopted in 2026 as follow-up to the ECI Communication "Fur Free Europe": • External study • Call for evidence	Launch Publication	In the course of 2025 In the course of 2025	External study was launched in June 2025 Call for evidence was published in July 2025

([19]) The list includes proposals led by DG SANTE that were announced as priority proposals in annex III of the 2025 Commission Work Programme and that were pending agreement by the co-legislators at end 2024.

ANNEX 3: Draft annual accounts and financial reports

The draft annual accounts and financial reports are made available through an online platform, which you can directly access:

https://dashboard.tech.ec.europa.eu/qs_digit_dashboard_mt/public/extensions/BUDG_Annex3/BUDG_Annex3.html.

ANNEX 4: Financial scorecard

The transition in 2025 to the Commission's new accounting system, SUMMA, has required the adjustment to a new system and has impacted budget implementation tasks, processes and financial management activities, particularly during the first part of the year. In some cases, this has resulted in lower performance for some standard financial indicators such as the timely payment.

The draft annual accounts and financial reports are made available through an online platform, which you can directly access:

https://dashboard.tech.ec.europa.eu/qs_digit_dashboard_mt/public/extensions/BUDG_Annex4/BUDG_Annex4.html.

ANNEX 5: Materiality criteria

With regard to budget implementation, the concept of materiality provides the authorising officer by delegation with a basis for determining significant weaknesses that should be subject to a formal reservation to the declaration of assurance. The criteria used in DG SANTE for making reservations are based on the standing instructions for the preparation of Annual Activity Reports.

Risks or weaknesses leading to a reservation should fall within the scope of the declaration which covers a narrower area than the AAR itself:

- ⇨ The AAR includes an assessment of the results achieved by DG SANTE with the resources allocated. It is a "mirror" image of DG SANTE's annual Management Plan (MP).
- ⇨ The declaration expresses the Director's General responsibilities conferred under the Charter for Authorising Officers by Delegation and is restricted to the following areas (i) control systems, (ii) sound financial management, and (iii) legality and regularity of transactions.

When defining whether a detected issue in internal control is material, DG SANTE assesses both qualitative and quantitative aspects:

1. Qualitative criteria

DG SANTE investigates the significance of any detected weakness and the expected potential for further weaknesses in qualitative terms by taking into account the nature and scope of the weakness, the possible impact of the weakness, as well as the existence of effective corrective actions.

1.1 Significant repetitive errors

Systematic errors caused by weaknesses in key controls and intentional misstatements are likely to entail a greater exposure to potential financial loss than random errors or faulty judgements. In the context of grant management and certain procurements, the exposure to potential financial loss is highest for errors in final payments. For errors in pre-financing payments, the risk is much lower because firstly, these funds remain the property of the EU and secondly, errors detected in pre-financing or interim payments can still be corrected at the final payment stage.

1.2 Significant deficiencies in one of the control systems

Identified weaknesses in the design or operation of internal controls of DG SANTE, final beneficiaries or Member States could significantly influence the appreciation of the Director's General Declaration.

This could be the case notably,

- if significant conflicts of interest existed;
- if personnel were unqualified;
- if the systems failed to provide complete and accurate information due to design flaws or misapplication of procedures;

- if appropriate verifications, approvals, reviews and audits of transactions and procedures were absent or largely insufficient or inadequate;
- if duties were not separated; or
- if controls were intentionally overridden and/or wilfully circumvented.

1.3 Issues outlined by auditors or OLAF

A critical observation made by the Court of Auditors, the Commission's Internal Audit Service (IAS) or OLAF could lead to a reservation,

- if the observation is made in an area covered by the Director General's Declaration, and
- if the issue is not solved immediately during the reporting period, and
- if the impact is material (financial loss exceeding 2 % of the implemented budget concerned (ABB activity; see point 2 below).

1.4 Significant reputational risks

Besides a possible quantitative aspect of a reputational risk, its impact on the declaration of assurance is assessed mainly on the basis of qualitative criteria, such as sensitivity of the policy area concerned, high public interest or serious legislative concerns. It encompasses issues that could cause lasting damage to the Commission's image due to, for example, financial fraud inside DG SANTE or serious breaches on provisions of legislation (including the Treaty), further to DG SANTE's activities.

2. Quantitative criterion

2.1 Erroneous transactions

In the framework of a transaction-based approach, DG SANTE considers that identified erroneous transactions which expose DG SANTE to an actual financial loss could lead to a reservation to the Director General's declaration under the following conditions:

(1) A significant weakness described in the AAR has been identified, and

(2) The weakness affects at least one the areas of the declaration of assurance: (i) control systems, (ii) sound financial management, or (iii) legality and regularity of transactions, and

(3) An actual financial loss or reputational issue has already occurred or is very likely to materialise, and

(4) The amount has actually exceeded or is very likely to exceed the threshold of 2 % of the relevant payment budget actually implemented, that means if the issue is not already corrected during the reporting period, for example by recovery orders or offsetting with future payments due.

For controls carried out in the form of financial audits (on-the-spot or remote) of payments,

- Errors found in ex-ante controls are typically corrected prior to the final payment.
- Errors found during ex-post controls (after the final payment) are called detected errors and are typically corrected by recovery orders or other kinds of corrections.

The detected error rate is the basis to estimate the risk at payment and the risk at closure.

2.2 Error rate calculation

For controls carried out in the form of financial audits (on-the-spot or remote) of payments, an error rate after corrective measures is called "residual error rate" The risk is calculated following Commission's guidelines built up along the lines of a "3+1 steps" approach and measured against the 2% materiality criterion.

Step 1: calculating the representative detected error rate in a sample of transactions and taking account of any corrections made for the calculation of the residual error rate in the entire population;

Step 2: estimating the financial exposure as (net) 'amount at risk' to the value of the relevant payments authorised during the reporting year, based on those error rates calculated for a population of transactions mostly authorised in previous years;

Step 3: relating the 'amount at risk' for the activity considered to the relevant (ABB) aggregation level for determining whether a reservation would be due;

Step 4: "if" a reservation is entered, then assessing its relative impact on the AOD's overall assurance and Declaration (the “scope”). The following 'de minimis' thresholds are applied: if the scope of the reservation is < 5% of total payments and the exposure is < EUR 5 million, then no financial reservation is to be made (without prejudice to a reservation for reputational reasons).

2.3 Non-representative sampling

To select the sample of transactions to be controlled on the spot, DG SANTE applies a risk based and targeted approach rather than a statistical random method that would comply with the criteria of samples' representativeness. The risk-based approach is considered more cost-effective given the heterogeneity and relatively small size of DG SANTE's audit population.

In this case the detected error rate is not representative and thus cannot be extrapolated to all payments made in the same policy area. When measuring against the 2% materiality level, DG SANTE calculates the weighted arithmetic average error rate from the audited sample and complements the information by a qualitative analysis of the origin, nature, impact and coverage of the errors found before deciding whether or not the materiality threshold of 2% is exceeded.

2.4 De minimis' threshold for financial reservations

Since 2019 ([20]), a ‘de minimis’ threshold for financial reservations has been introduced. Quantified annual activity report reservations related to residual error rates above the 2% materiality threshold are deemed not substantial for segments representing less than 5% of a department’s total payments and with a financial impact below EUR 5 million. In such cases, quantified reservations are no longer needed. Cases where the ‘de minimis’ threshold applies this year are reported in annex 9.

([20]) Agreement of the Corporate Management Board of 30/4/2019.

ANNEX 6: Relevant Control System(s) for budget implementation (RCSs)

Annex 6 covers the relevant control systems for budget implementation in DG SANTE related to the direct and indirect management. The Annex is divided into two parts as follows:

1) **Internal Control Templates for Direct Management** (grants and procurement);
2) **Internal Control Templates for entrusted entities and Indirect Management.**

ANNEX 6.1 Internal Control Template for direct management

This annex is divided into two parts, firstly, DG SANTE's relevant control systems related to grants in the Food Safety policy area and secondly, DG SANTE's relevant control systems for public procurement procedures.

1. Type of expenditure: grants to Member States in direct management

DG SANTE co-finances Member States' veterinary and phytosanitary emergency measures through the reimbursement of eligible costs. Applicable as from 1 January 2021, the SMP – Food Safety strand is the main basis for the corresponding expenditure ([21]). For actions initiated under the previous legislation ([22]), its provisions continue to apply until their closure.

The following internal control template only covers grants under the veterinary and phytosanitary emergency measures as these account for about 99% of all grants in both policy areas under DG SANTE's financial management in 2025.

This annex presents in schematic form the characteristics of the main management and control systems put in place by DG SANTE.

- Information on the costs and benefits of control is not always available for each single control stage, but for the process as a whole.
- Most of the benefits of control are non-quantifiable as they help ensure compliance and good quality of the funded actions which is impossible to quantify.
- For some control indicators, mere numbers and percentages do not give reliable information on the control effectiveness; only a qualitative analysis of the reasons behind the figures is relevant and useful.

([21]) Regulation (EU) 2021/690 of the European Parliament and of the Council of 28 April 2021 on the Single Market Programme (SMP) and repealing – inter alia - Regulation (EU) No 652/2014 the Common Financial Framework (CFF); 2021 work programme C(2021)3046 of 6 May 2021.

([22]) Common Financial Framework (CFF): Regulation (EU) No 652/2014.

Grants for veterinary and phytosanitary emergency measures				
Main inherent risks	Mitigating controls	Control coverage	Costs and benefits of controls	Cost-Effectiveness indicators
Stage 1 Legal base and Member States' submission of applications				
Main control objectives: ensuring that the Commission finances emergency measures that are eligible and contribute towards the achievement of the policy objectives (effectiveness and best value for public money); compliance (legality & regularity); prevention of fraud (anti-fraud strategy)				
Eligibility, selection and award criteria should be adequate to achieve the SMP objectives: avoidance of further spread of the animal diseases and plant pests and, their fast eradication	- The SMP (Regulation (EU)2021/690 sets out the eligibility, selection and award criteria; - Grants may be awarded to Member States and third countries in case of emergency measures taken as a result of confirmed occurrence of a number of listed diseases - The award criteria for the financial contribution by the Union are: a) compliance with the requirements of the relevant Union law; b) relevance of the planned activities in view of the prevention or eradication of the animal diseases and plant pests; c) activities related to prevention or eradication of plant pests during the first year after the detection of the outbreak. - Costs incurred by the Member States shall be eligible prior to the date of submission of the grant application according to Article 13(1) of the SMP: derogation from the principle of non-retroactivity pursuant to Article 196 FR(2024).	The risks at stage 1 are assessed as low as the selection and attribution criteria, the submission modalities and the list of eligible measures are set out in the legislation.	**Cost of control**: Estimate of DG SANTE's staff costs for handling the Member States' applications **Benefits of control:** As no significant errors are to be expected, the benefits are mainly administrative in nature and thus non-quantifiable in budgetary terms	(%) Number of successfully implemented emergency measures on plant pests and animal diseases (SMP, Annex IV) ð Target: 100% successfully implemented

Grants for veterinary and phytosanitary emergency measures				
Main inherent risks	Mitigating controls	Control coverage	Costs and benefits of controls	Cost-Effectiveness indicators
Member States' applications should be timely, of good technical quality and include reliable estimates of the eligible costs of the emergency measures to ensure sound financial management	1. Article 13 of the SMP sets out that the submission of the grant application shall be preceded by the notification to the Commission of the occurrence of the disease in accordance with Regulation (EU) 2016/429 for animal diseases and Regulation (EU) 2016/2031 for plant pests (within a certain period of time from the official confirmation of the occurrence of the disease or presence of the pest, Member States shall provide preliminary information on the ongoing and planned actions, on the estimated total eligible costs (as defined in the SMP, annex I) and on the expected date of the end of the completion of the emergency measures); 2. DG SANTE provides templates for the Member States' submissions of applications and guidelines (e.g. on the eligibility of costs); 3. The technical and financial parts of each application are checked by the competent operational and financial officers to ensure that the Member States' ongoing and planned emergency measures are adequate and their cost estimates reasonable; 4. The Member States send to DG SANTE on a regular basis updated information on the eligible costs of the emergency measures taken to fight the outbreak.			

Grants for veterinary and phytosanitary emergency measures				
Main inherent risks	Mitigating controls	Control coverage	Costs and benefits of controls	Cost-Effectiveness indicators
Stage 2 "Contracting": approving the emergency measure and signing the grant agreement				
Main control objectives: ensuring that the actions and funds allocation is optimal (best value for public money; effectiveness, economy, efficiency) and compliant (legality & regularity)				
The grant agreements for emergency measures should: (a) be timely, (b) include reasonable funding (c) correspond to DG BUDG template (as much as possible)	1. After the official confirmation of the occurrence of the disease or presence of the pest, DG SANTE invites the Member States to submit their applications for a grant agreement; 2. DG SANTE evaluates each application (technical and financial aspects) and documents the results in checklists; 3. The Authorising Officer responsible informs DG SANTE's management (Food Sustainability Network) in writing on the allocation of credits per Member State and disease; 4. The Authorising Officer responsible takes the award decision defining the beneficiary and the grant amount based on the technical and financial assessment; 5. Following ex-ante checks on administrative and legal aspects of the grant agreement, the Authorising Officer responsible approves formally in a grant agreement the Member States application and its associated funding. 6. The grant agreement is countersigned by the Member State. 7. No budgetary commitment is done at this stage according to Article 4(5) SMP, by way of derogation from Article 111(2) of the Financial Regulation (2024).	1.-2. 100% of applications to be technically and financially approved prior to preparing the grant agreement; 3.-5. 100% of grant agreements checked prior to approval (depth of checks depends on risk criteria) 6. 100% countersigned by the Member State 7. No budgetary commitment at this stage	**Cost of control:** Included in estimate of DG SANTE's staff costs for handling the Member States' applications **Benefits of control:** Compliance	*(comment: the timing for signing grant agreements depends on the availability of budget; hence, no target dates can be fixed)*

Grants for veterinary and phytosanitary emergency measures				
Main inherent risks	Mitigating controls	Control coverage	Costs and benefits of controls	Cost-Effectiveness indicators
Stage 3: Managing financial transactions and ex-ante controls				
Main control objectives: ensuring that the related financial operations comply with regulatory and contractual provisions (legality & regularity); prevention of fraud (anti-fraud strategy); ensuring appropriate accounting of the operations (reliability of reporting, safeguarding of assets and information)				
Controls should prevent that ineligible amounts are paid and ensure that derogations from the Financial Regulation as set out in the SMP are applied correctly.	1. By the date stipulated in the grant agreement, the Member States shall submit their payment applications (cost claims); 2. DG SANTE assesses the technical and financial aspects of the payment applications and documents the results in checklists. Special attention is paid to the following provisions in the SMP Article 13 (1): "emergency measures (a) shall be eligible prior to the date of submission of the grant application in accordance with Article 196(2), second subparagraph, point (b) of the Financial Regulation (2024); (b) shall be eligible from the date of the suspected occurrence of an animal disease or the presence of a plant pest, provided that that occurrence or presence is subsequently confirmed." 3. Financial transactions are launched in SUMMA, while paying special attention to the correct application of the following provision in the SMP: Article 3(5): "By way of derogation from Article 111(2) of the Financial Regulation, the Commission shall make the budgetary commitment for the grant awarded for veterinary and phytosanitary emergency measures (…)	1.-2. All payment applications are assessed (technical and financial checklists completed; the control depth depends on risk criteria) 3. Further to a risk assessment, a number of cost claims is subject to an ex-ante financial control on-the-spot (see stage 4 below); 4. 100% of payments and SUMMA encodings 5. 100% if conditions are fulfilled	**Cost of control:** Included in the estimate of DG SANTE's staff costs for handling the Member States' applications **Benefits of control:** Compliance	- Files with relevance for OLAF adequately transmitted to OLAF and followed up ð Target: 100% - Time between receipt of the Member States' payment application and the payment ð Target: 95% payments on time (in number and in amount)

Grants for veterinary and phytosanitary emergency measures				
Main inherent risks	Mitigating controls	Control coverage	Costs and benefits of controls	Cost-Effectiveness indicators
	after the payment applications submitted by Member States have been assessed." 4. Payments follow DG SANTE's financial circuits with financial verifications, authorisations and encodings in SUMMA; they are in the scope of the European Court of Auditors (ECA)'s annual financial audits; 5. If deemed necessary, the file is referred to OLAF (DG SANTE's SOPs apply).			
Stage 4: Financial audits (ex-ante and ex-post) "on the spot"				
Main control objectives: (a) Detect and correct any error or fraud remaining undetected after standard ex-ante controls (legality & regularity; anti-fraud strategy); addressing systemic weaknesses in the ex-ante controls, based on the analysis of the findings (sound financial management); ensuring appropriate accounting of the recoveries to be made (reliability of reporting, safeguarding of assets and information); (b) Ensuring that the (audit) results from the ex-post controls lead to effective recoveries (legality & regularity; anti-fraud strategy); ensuring appropriate accounting of the recoveries made (reliability of reporting).				
Certain issues (errors or attempted fraud) cannot be detected and corrected during standard ex-ante desk controls; thus, **controls carried out in the form of financial audits (on-the-spot or remote)** should complement	DG SANTE's financial audit strategy aims at optimising the control impact through a risk-based selection of grants to be audited either ex-ante or ex-post and a sufficient audit coverage to lower the residual error rate. Preference is given to ex-ante rather than ex-post audits of emergency measures, due to the fact that unforeseeable developments in any emergency situation entail a relatively high uncertainty of whether or not a measure is eligible. 1. Financial audits are carried out by competent staff independent of the policy Unit and according to professional standards; the audit programmes foresee anti-fraud measures;	- Risk based audit sample 1. High coverage (>50%) of cost claims by ex-ante audits to maximise corrections prior to the final payment; 2. 100% of audit reports; 3. 100% if conditions are fulfilled	**Cost of control**: Estimated staff costs for financial audits Cost of external audit services **Benefits of control:** Value of the financial corrections made further to the audits	- Detected correction rate in case of ex-ante controls ð Target: decreasing trend - Residual error rate ð Target: < 2% - Number of files referred to OLAF ð Target: 0

Grants for veterinary and phytosanitary emergency measures				
Main inherent risks	Mitigating controls	Control coverage	Costs and benefits of controls	Cost-Effectiveness indicators
the standard desk checks ([23]).	2. All audit reports undergo a contradictory procedure within DG SANTE and with the auditees (i.e. Member States); 3. If deemed necessary, the file is referred to OLAF (DG SANTE's SOPs on handling allegations of fraud and contacts with OLAF).			
Detected errors, irregularities or suspicions of fraud should be **addressed adequately and in a timely manner.**	1. Communication and registration of all audit results to management (e.g. in annual reports); 2. Financial and operational validation of recovery orders or payments following DG SANTE's financial circuit; 3. Exceptions and internal control weaknesses are reported and analysed; 4. Follow-up on audit recommendations addressed to SANTE linked to emergency measures (ECA and IAS).	1. 100% of final control results 2. 100% financial control of recovery orders 3. 100% of financial procedures 4. 100% of accepted recommendations implemented	**Cost of control**: Included in the estimated staff costs for handling the Member States' applications **Benefits of control:** Amount of actually corrected errors	- Audit results implemented ð Target: 100% - "Time to recover" from final accepted audit report to debit note ð Target: 100% without undue delay - Ratio of accepted audit recommendations (ECA and IAS) implemented on time ð Target: 90%

([23]) In 2024, DG SANTE did not perform any ex-post controls for grants.

2. Type of expenditure: procurement in direct management

Following the transfer of implementation tasks to the Health and Digital Executive Agency (HaDEA), public procurement in relation to the Public Health programmes as well as the procurement procedure for the initiative “Better Training for Saver Food” (BTSF) under the Single Market Programme is managed by the agency. Consequently, the number of contracts managed by DG SANTE is limited.

The majority of the procurement procedures are based on framework contracts of DG SANTE or another DG, in particular DGs DIGIT, COMM and BUDG. DG SANTE buys mainly services in the area of data collection, evaluation, training, information campaigns, IT and communication services, facilities management etc. The contractors are mainly institutes, laboratories, consultancy firms and other private companies. DG SANTE also buys vaccines and antigens for animal diseases under the Single Market Programme-Food Chain strand.

The control costs associated with safeguarding assets, such as IT software developed by DG SANTE, are considered marginal and do not warrant a separate control system. Therefore, they are included in procurement under direct management. Throughout the financial year, IT project costs are meticulously tracked and monitored with the cooperation of DG BUDG. More controls referring to IT assets, ensuring that they are tracked, secured, and used effectively, are covered in the European Commission’s Digital Strategy.

This annex presents in schematic form the characteristics of the main management and control systems put in place by DG SANTE.

- Information on the costs and benefits of control is available for the entire control process, but not always for each single control stage.
- Most of the benefits of control are non-quantifiable as they help ensure compliance and good quality of the funded actions which is impossible to quantify.
- For some control indicators, mere numbers and percentages do not give reliable information on the control effectiveness; only a qualitative analysis of the reasons behind the figures is relevant and useful.

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Public Procurement				
Main inherent risks	Mitigating controls	Control coverage	Costs and benefits of controls	Cost-Effectiveness indicators
Stage 1a) Programming: legal base; 1b) Needs assessment and definition of needs; 1c) Selection of the offers and evaluation				
Main control objectives: ensuring sound financial management (i.e. effectiveness, efficiency and economy); compliance (legality & regularity); prevention of fraud (anti-fraud strategy)				
Needs have to be well defined (operationally and economically) and decision to procure have to be appropriate to meet the operational objectives. Poor planning or inadequate organisation of the procurement procedure could entail delays or interruptions of services leading to an underachievement of the policy objectives.	1. For operational credits in each policy area, a detailed annual or multi-annual work programme is adopted by the Commission specifying the areas for which calls for tenders or calls for proposals will be organised; it constitutes a financing decision; 2. Planned external studies are listed in a register kept by the Secretariat General; 3. Each call for tenders fixes either a maximum value or a price range for the contract based on a pricing methodology; 4. The timing and organisation of a procurement procedure is supervised by the Authorising Officer responsible; 5. Timing is monitored, and planning updated through budget implementation reports prepared by the central financial Unit for discussions in Directors' Steering Committees at least two times a year; 6. Procurement procedures are managed through eProcurement, mainly the Public Procurement Management Tool (PPMT).	1. 100% of calls for tender are covered by a Commission financing decision. 2. 100% of external studies are listed in a special register at the level of the Secretariat General. 3. All calls for tender are based on a pricing methodology (depth depending on feasibility). 4-5. All public procurements in the annual work programmes are approved by Management 6. Use of eProcurement when applicable or deviation justified	**Cost of control**: Estimated staff costs for programming and planning and execution of the procurement procedures. **Benefits of control:** Amount of rejection of unjustified purchases or services discontinued.	- Depth of price calculation using the pricing methodology (according to template) when applicable ð Target: 100% in-depth where applicable - Timely launch of procurement procedures as specified in the annual work programmes ð Target: 100%

Public Procurement				
Main inherent risks	Mitigating controls	Control coverage	Costs and benefits of controls	Cost-Effectiveness indicators
If the definition of tender specifications, exclusion, selection and award criteria are poor, or if the publication of a tender is insufficient, the best possible bids might not be received.	1. To ensure a high level of expertise in drafting the tender specifications, DG SANTE competent staff of the policy Units write the specifications with the support of the central procurement team in the horizontal Directorate; 2. DG SANTE uses templates for terms of reference, exclusion and selection criteria that follow the Commission guidelines; the central procurement team organises the entire process and does a quality control; 3. The central procurement committee (CMP) reviews the tender specifications prior to publication for certain sensitive procurements on special request of the policy Unit; 4. The tender specifications are validated by the Authorising Officer responsible who launches the publication of the tender in pre-defined means.	1. Tender specifications are drafted in the Units concerned with central support on request (depth of the support depending on needs) 2. 100% where applicable 3. Central ex-ante review of tender specifications on special request 4. 100% validation by Authorising Officer	**Cost of control**: Estimated staff costs for drafting tender specifications **Benefits of control:** Value of a contract, possibly at 100% if significant errors occurred "Best value for money" is non-quantifiable as quality aspects are impossible to quantify reliably.	- Number of open calls for tenders for which no offer is received (reasons to be analysed) ð Target: 0% - Number of cancellations of open tender procedures (reasons to be analysed) ð Target: 0% -Timeliness of procurement procedures relative to Commission Work Programmes
The most economically advantageous offer should be selected, and the **evaluation process** should be **unbiased, fair and without error.**	1. The central procurement team in the horizontal Directorate organises the opening and evaluation procedures, sees to their correct implementation and documentation; members of committees are appointed by the Authorising Officer responsible; 2. Persons involved in the formal procedures sign declarations of absence of conflict of interest; 3. Bidders are checked against exclusion and selection criteria published with the tender specifications; 4. The central procurement committee examines open call tender procedures > €139 000 (in 2021) and	1. 100% of tender procedures are documented; for 100% of tender procedures > €60.000 committees are formally appointed 2. 100% of evaluators 3. 100% of bidders checked	**Cost of control**: Estimated staff costs in the evaluation process **Benefits of control:** Value of a contract, possibly at 100% if significant errors occurred Benefit of "best value for money" is non-quantifiable as quality	- Number of valid complaints, Ombudsman cases or litigations received ð Target: 0% - Number of cancellations of open tender procedures due to errors in evaluation process ð Target: 0%

Public Procurement				
Main inherent risks	Mitigating controls	Control coverage	Costs and benefits of controls	Cost-Effectiveness indicators
If procedures are not correctly followed, DG SANTE could be facing possible litigation and /or reputational damage.	gives an independent opinion to the Authorising Officer responsible; 5. The Authorising Officer responsible validates the evaluation results and takes the award decision; 6. After the award decision, a standstill period of two weeks applies in certain procedures before the contract is signed to give unsuccessful tenders the opportunity to raise concerns.	4. For 100% of open call tender procedures above the threshold the CMP gives an opinion 5. 100% validated 6. 100% if conditions are fulfilled	aspect is impossible to quantify reliably.	
Stage 2: Monitoring of the implementation of the contract and financial transactions				
Main control objectives: ensuring that the implementation of the contract is compliant with the signed contract and that the purchased products or services are of good quality and meet the contract's objectives and conditions (effectiveness & efficiency); ensuring that the related financial operations comply with regulatory and contractual provisions (legality & regularity); prevention of fraud (anti-fraud strategy); ensuring appropriate accounting of the operations (reliability of reporting, safeguarding of assets and information)				
The purchased products or services should be provided in accordance with the technical requirements and the contractor should deliver within the set schedule and price range.	1. The contract provisions follow the model contract of the Commission; 2. Competent staff monitors the implementation of the contract and the progress made (frequency and depth depending on the size and sensitivity of the contract); 3. Technical implementation reports are assessed and validated prior to initiating payments; 4. DG SANTE makes use of contractual provisions for refusing technical reports, cutting payments, termination of the contract, penalties etc.; 5. Financial checks prior to payment are carried out according to DG SANTE's financial circuits with financial verifications, authorisations and encodings in SUMMA.	1 to 4. 100% covered by model contracts, monitoring of progress, financial circuits with assessment and validation of technical and financial reports (control depth depends on risk criteria); 5. 100% if conditions are fulfilled	**Cost of control**: Estimated staff costs for monitoring and financial transactions. Mission costs for monitoring activities **Benefits of control:** Estimated value of the financial corrections made during ex-ante controls of the final payment. Benefit of "best value for money" is non-quantifiable as	- Time-to-pay ð Target: 100% on time - Rate of late interest or damage payments to total value of all procurement contracts ð Target: 0%

Public Procurement				
Main inherent risks	Mitigating controls	Control coverage	Costs and benefits of controls	Cost-Effectiveness indicators
	6. If deemed necessary, the file is referred to OLAF (DG SANTE's SOPs on handling allegations and contacts with OLAF).		quality aspect is impossible to quantify reliably.	
Stage 3: Supervisory measures				
Main control objectives: Measuring the effectiveness of ex-ante controls by supervisory controls; ensuring to detect and correct any error or fraud remaining undetected after the implementation ex-ante controls (legality & regularity; anti-fraud strategy); addressing systemic weaknesses in the ex-ante controls, based on the analysis of the findings (sound financial management); ensuring appropriate accounting of the recoveries to be made (reliability of reporting, safeguarding of assets and information)				
In some cases ex-ante controls at the desk might fail to prevent, detect and correct errors in procurement procedures or attempted fraud; **other internal controls** should be designed to prevent, detect or mitigate negative effects ([24]).	1. DG SANTE's financial audit strategy includes procurement contacts only in exceptional cases (e.g. exceptionally high amounts or other high risks); the audit work programme foresees anti-fraud measures; 2. Follow-up on audit recommendations linked to procurement (ECA and IAS); 3. Exceptions and internal control weaknesses are reported and analysed; 4. The management of sensitive functions is centralised to ensure independent analysis and judgment; 5. If deemed necessary, the file is referred to OLAF (DG SANTE's SOPs on handling allegations and contacts with OLAF).	1. Risk based audit sample (no minimum audit coverage foreseen as only on exceptional basis) 2. 100% of accepted recommendations implemented within the deadlines 3. 100% of financial procedures 4. High risk operations 5. 100% if conditions are fulfilled	**Cost of control**: Estimated staff costs for ex-post controls, internal audits and other supervisory controls; Estimated mission costs for audits or other controls; Cost of external audit services **Benefits of control:** Value of the financial corrections made during ex-post audits or controls	- Detected error rate ð Target: decreasing trend - Ratio of accepted audit recommendations (ECA and IAS) implemented on time ð Target: 100% - Ratio of corrected control weaknesses to total detected weaknesses in procurement procedures ð Target: 100% - Average cost per audit to average amount of audit correction ð Target: > 100%

([24]) In 2025, DG SANTE did not perform any ex-post controls for procurement.

This segment also includes administrative expenses for salaries and/or missions, which are reported by the service responsible for the commitment, although the payments are executed by another service, notably the PMO and/or DG HR ([25]). The executing service implements the necessary technical-level controls and submits a declaration to DG SANTE on the compliance of these payments with the principle of sound financial management, as well as their legality and regularity. These expenses are considered to present a low level of risk and are therefore subject to a flat rate of 0.5%, as corroborated by the control results of the executing service(s). More information on the implemented controls can be found in the [DG HR/PMO] annual activity report(s).

([25]) Type III co-delegation for which these expenses were reported by the service executing the payments until 2024.

Annex 6.2 Internal Control Template for entrusted entities and indirect management

This annex is divided into the following three parts:

1) ***The executive agency HaDEA*** *(direct management);*

2) ***Contribution agreements with international organisations and decentralised agencies*** *(indirect management);*

3) ***Subsidy payments to EU decentralised agencies*** *under the remit of DG SANTE.*

1. DG SANTE delegated budget implementation tasks to HaDEA

The Health and Digital Executive Agency (HaDEA) ([26]) implements for DG SANTE – direct management – large parts of the:

(a) EU4Health Programme budget and;

(b) Food chain strand of the SMP budget.

DG SANTE is the lead parent DG for the agency and paid subsidies to finance – partially or in full – the operating budget of HaDEA's running costs; the other parent DGs also pay their parts.

DG SANTE's control strategy for HaDEA encompasses both the delegated EU funds and the subsidy payments to the executive agency's operating budget as for both transactions the same internal control system applies.

For some control indicators, mere numbers and percentages do not give reliable information on the control effectiveness; only a qualitative analysis of the reasons behind the figures is relevant and useful.

([26]) C(2021)948 of 12 February 2021 – Commission Decision on delegating powers to HaDEA.

Budget implementation tasks delegated to the executive agency HaDEA				
Main inherent risks	Mitigating controls	Control coverage	Costs/benefits of controls	Cost-Effectiveness indicators
Stage 1. "Mandate of the entrusted entity": establishment, prolongation or adjustment of the delegation act of the executive agency				
Main control objectives: ensuring that the legal framework for the management of the relevant funds is fully compliant and regular (legality & regularity), delegated to an appropriate entity (best value for public money, economy, efficiency), without any conflicts of interests (anti-fraud strategy)				
Establishment (or prolongation) of the mandate of the executive agency should be free of any legal issues, as these could undermine the legal basis for the agency's management of the EU funds transferred to it.	The legal framework ("statute") for executive agencies is laid down by Council Regulation (EC) 58/2003. HaDEA was established by Commission Implementing Decision (EU) 2021/173 of 12 February 2021. 1. A cost-benefit study was carried out by Commission services prior to HaDEA's establishment; 2. The Member State Committee for executive agencies approved the Commission's proposals for establishing the agency; 3. DG SANTE follows the Commission's models for the decisions on establishment and task delegation to the agency; 4. DG SANTE manages the interservice consultations and publications of the Commission Decisions.	**100% in-depth** controls at each stage on DG SANTE's and DG BUDG's side **Frequency:** Once in 2021 when the agency was established. Each time when the mandate of the agency is prolonged.	**Cost of control**: Estimated SANTE staff costs for technical, financial and legal preparation of the agency's mandate, approval by the Member State Committee and adoption by the Commission. **Benefits of control:** The total budget amount delegated to the agency per year possibly at 100% if significant legal errors occurred.	Number of legal issues a/o negative opinions during the interservice consultation ð Target: 0 Quality of the legal work not challenged by auditors or OLAF ð Target: 0 Timely adoption of all necessary legal acts for the establishment and future extensions of the agency's mandate

Budget implementation tasks delegated to the executive agency HaDEA				
Main inherent risks	Mitigating controls	Control coverage	Costs/benefits of controls	Cost-Effectiveness indicators
Stage 2. Readiness assessment of the executive agency's control framework towards autonomy				
Main control objectives: ensuring that the entrusted entity is fully prepared to start/continue implementing the delegated funds autonomously respecting the five control objectives set forth in the Financial Regulation: (i) legality and regularity, (ii) sound financial management, (iii) true and fair view reporting, (iv) safeguarding assets and information, (v) anti-fraud strategy				
Financial and control framework deployed by the executive agency should be fully mature to guarantee that the control objectives are met.	1. All parent DGs agreed on an ex-ante assessment of the agency's internal control system prior to granting full budget autonomy. This exercise will be repeated for subsequent prolongations and amendments of the agency's mandate if this entails substantial change to the agency's control systems; 2. According to HaDEA's Act of Delegation (C(2021)948 of 12 February 2021), the agency submits to DG SANTE for approval any substantial change in its manuals and procedures, in its model grant agreements and procurement contracts. This is done through the Steering Committee.	1. **100% in-depth** control once when the agency was set up 2. Each request for substantial change is examined in-depth **Frequency:** when applicable	**Cost of control:** Estimated staff costs for ex-ante assessment when agency is established **Benefits of control:** The total budget amount delegated to the agency per year possibly at 100% if significant legal errors occurred	-Granting budget autonomy without significant delay ð Target: when applicable -Time between establishment of the agency and granting of autonomy ð Target: 100% on time according to internal planning
Stage 3: Agency's operations: DG SANTE's monitoring and supervision ("control *with* the executive agency")				
Main control objectives: ensuring that DG SANTE is fully and timely informed of any relevant management issues encountered by the executive agency, in order to possibly mitigate any potential financial and/or reputational impacts				
DG SANTE should be informed timely of relevant management issues encountered by	The **Act of Delegation** specifies the agency's management tasks and duties, including internal control and risk management systems, and modalities on reporting relevant and reliable control results. The Act of Delegation also specifies DG SANTE's scrutiny rights and obligations, including documentary and on-the-spot checks and audits at the agency.	**Coverage**: 100% of the tasks delegated to the agency monitored and supervised **Depth of control**: risk	**Cost of control**: Estimated SANTE staff costs for monitoring and supervising the agency's activities Mission costs for monitoring activities	-Regular programme meetings between the agency and DG SANTE at operational level ð Target: to be defined per delegated programme -Steering Committee meetings with adequate quorum for voting

Budget implementation tasks delegated to the executive agency HaDEA				
Main inherent risks	Mitigating controls	Control coverage	Costs/benefits of controls	Cost-Effectiveness indicators
the executive agency; DG SANTE should react upon notified issues timely and adequately. If not, this could reflect negatively on the Commission's reputation.	1. Regular meetings take place between the agency and SANTE at the level of the Units concerned and monthly meetings at Director; 2. A general **Memorandum of Understanding** (MoU) for the day-to-day co-ordination between the parent DGs and the agency was signed in December 2021; the MoU is complemented by specific guidelines for SANTE delegated tasks; 3. The **Steering Committee**, chaired by DG SANTE, meets at least four times a year and adopts (i) the agency's annual work programme, after approval by the Commission, and (ii) the draft administrative budget, including the establishment plan, after adoption of the general EU budget by the budgetary authority; 4. The agency reports at mid-term to the Steering Committee on the performance of its tasks; the parent DGs give feedback within four weeks; 5. DG SANTE's central financial Unit reports regularly on the implementation of the budget delegated to the agency; 6. The agency's Annual Activity Report follows the Commission's instructions, is adopted by the Steering Committee and published in the same way as DG SANTE's Annual Activity Report; 7. If deemed necessary, issues are referred to OLAF (DG SANTE's SOPs on handling allegations and contacts with OLAF).	based; DG SANTE has full access to the agency's internal control information, if need be **Frequency**: quarterly, annually and in day-to-day contacts as deemed necessary	**Benefits of control:** The total budget amount delegated to the agency per year possibly at 100% if significant legal errors occurred	ð Target: 4 times a year -Reported monitoring issues, supervisory control failures and/or exception reports relative to DG SANTE's monitoring of and co-operation with the agency ð Target: qualitative analysis of reasons for the reported issues -Budget execution rates of the operational budget transferred to the agency and absorption rate of global commitments ð Target: 99% commitments and absorption of global commitments ð Target: 100% for payments -Director's mid-term report on control results and error rates endorsed by Steering Committee within 4 weeks ð Target: qualitative analysis -Timely endorsement by the Steering Committee of the agency's annual work programme and administrative budget (target: December N-1 at the latest) ð Target: 100% on time

Budget implementation tasks delegated to the executive agency HaDEA				
Main inherent risks	Mitigating controls	Control coverage	Costs/benefits of controls	Cost-Effectiveness indicators
Stage 4: DG SANTE's payment of the subsidy – the agency's operating or administrative budget				
Main control objectives: ensuring that DG SANTE fully assesses the management situation at the agency, before either paying out the (next) instalment of the subsidy to the agency or deciding to cut, suspend or interrupt the (next) payment (legality & regularity, sound financial management, anti-fraud strategy)				
DG SANTE might not be aware of management issues that could lead to financial and/or reputational damage for the Commission as it pays the subsidy to the agency.	1. On the basis of the agency's annual budget and work programme adopted by the agency's Steering Committee, DG SANTE pays the subsidy to the agency's administrative budget in several instalments: - An instalment is paid in year N on request of the agency based on a cash forecast; - Prior to the subsidy payment, financial checks are carried out according to DG SANTE's financial circuits with financial verifications, authorisations and encodings in SUMMA; 2. All instalments remain pre-financing payments until the agency's accounts have been audited by the European Court of Auditors and the agency has submitted its final accounts (in general by July N+1); 3. On the basis of the agency's final accounts, DG SANTE clears all pre-financing payments in year N+1 and, if applicable, recovers unspent amounts of the instalments paid to the agency; no additional payment is made.	**Coverage**: 100% of DG SANTE's subsidy payments through the established financial circuits **Depth** of control: risk based **Frequency**: Administrative budget of the agency annually audited by the Court of Auditors	**Cost of control**: Estimated staff costs for budget and finance in central financial Unit **Benefits of control:** The total subsidy paid to the agency per year possibly at 100% if significant legal errors occurred	-Number of reported monitoring issues, incidences of payment suspensions or reductions and/or exception reports relative to DG SANTE's subsidy payment to the agency ð Target: qualitative analysis of reasons for the reported issues; all issues adequately followed up -Ratio of recovery of the positive budgetary outturn of year N on subsidy paid in year N-1 -Files with relevance for OLAF adequately transmitted to OLAF and followed up ð Target: 100% -Time-to-pay (target: maximum 30 days) ð Target: 100% on time

2. Contribution agreements with international organisations and decentralised agencies

Under indirect management, candidate entities to be entrusted with budget-implementation tasks must demonstrate a level of financial management and protection of the EU financial interests equivalent to that required when the Commission manages European Union funds. This is verified by carrying out an ex-ante assessment ("pillar assessment") for which the entities concerned must have been assessed positively.

DG SANTE manages contribution agreements with international organisations that are pillar assessed as well as with decentralised agencies under its remit, and that have been chosen in accordance with the EU4Health Regulation (EU) 2021/522, Articles 7(1) and 13(1) point (b), and the SMP Regulation (EU) 2021/690, Articles 6(1) and 9(2) point (b).

Contribution agreements with international organisations and decentralised agencies				
Main inherent risks	Mitigating controls	Control coverage	Costs and benefits of controls	Cost-Effectiveness indicators
Stage 1 Prior to contracting: ex-ante (re)assessment of the international organisation's financial and control framework (towards "budget autonomy"). ***As regards Decentralised agencies, this stage is covered by Stage 1 and 2 of the RCS "Subsidy payments to EU decentralised agencies".***				
Main control objectives: ensuring that the international organisation is fully prepared to start/continue implementing the delegated funds autonomously demonstrating a level of financial management and protection of the EU financial interest equivalent to that of the Commission				
The **financial and internal control framework** of the international organisation should be fully mature to ensure legality and regularity, sound financial management, true and	Ex-ante pillar assessment, conditional to granting budget autonomy. DG SANTE does not conduct own pillar assessments itself but contributes to and relies on assessments conducted by other DGs.	**Coverage/frequency**: 100% of international organisations pillar assessed; Depth may be determined based on the type or nature of the organisation	**Cost of control**: Estimate of DG SANTE's staff costs for contributing to pillar assessments **Benefits of control:** Compliance (non-quantifiable in budgetary terms)	-(%) of timely contributions given to pillar assessments of the lead DG ð Target: 100% timely contributions -(%) of international organisations compliant with the pillar assessment ð Target: 100% compliant

Contribution agreements with international organisations and decentralised agencies				
Main inherent risks	Mitigating controls	Control coverage	Costs and benefits of controls	Cost-Effectiveness indicators
fair view reporting, safeguarding assets and information, anti-fraud strategy.		and/or the value of the budget concerned.		
Stage 2 "Contracting": preparing and signing the contribution agreement with the international organisation/decentralised agency				
Main control objectives: ensuring that the legal framework for the management of the relevant funds is fully compliant and regular and delegated to an appropriate entity (best value for public money, economy, efficiency), without any conflicts of interests				
Contribution agreements should: - be **signed timely** as indicated in the work programmes of EU4H and SMP, - be **evaluated** in an unbiased way, fair and without error to ensure good quality and reasonable funding - correspond to the **corporate template** (as much as possible) If procedures are not correctly followed, DG SANTE could be facing possible litigation and	1. During the preparations of the work programmes for the EU4Health and SMP, actions, their funding and the organisations who should implement them are identified by the policy Units and approved by the Authorising Officer by Delegation; each work programme is subject to interservice consultation for a Commission Decision; 2. Implementing the adopted work programme, DG SANTE invites the identified organisation/agency to submit its proposal; templates are used that comply with corporate models; 3. DG SANTE evaluates and "negotiates" the proposals (technical and financial aspects) and documents the results in checklists; 4. Based on the outcome of the evaluation, and following ex-ante checks on administrative and legal aspects of the contribution agreement, the Authorising Officer	1.-3. 100% of proposals to be technically and financially approved prior to preparing the agreement 4.-5. 100% of agreements checked prior to approval (depth of checks depends on risk criteria)	**Cost of control:** Included in estimate of DG SANTE's staff costs (financial and operational) for handling contribution agreements **Benefits of control:** Compliance (non-quantifiable in budgetary terms)	-(%) of timely signature of contribution agreements as included in the work programmes of the EU4Health and SMP ð Target: 100% timely signature -(%) of compliance with corporate models and guidelines applicable for contribution agreements under indirect management (except in justified cases) ð Target: 100% compliance

Contribution agreements with international organisations and decentralised agencies				
Main inherent risks	Mitigating controls	Control coverage	Costs and benefits of controls	Cost-Effectiveness indicators
/or reputational damage.	responsible approves and signs the contribution agreement; 5. The contribution agreement is countersigned by the international organisation/decentralised agency.			
Stage 3: Monitoring the implementation of the contribution agreement and managing financial transactions				
Main control objectives: ensuring that the Commission is fully and timely informed of any relevant management issues encountered by the international organisation/decentralised agency, to mitigate any potential financial and/or reputational impacts (legality and regularity, sound financial management, true and fair view reporting, anti-fraud strategy)				
The actions to be carried out by the international organisation / decentralised agency should comply with the **technical requirements** delivered within the set schedule and quality and compliant with the EU co-financing rules.	1. The agreements specify the requirements on reporting issues related to control, accounting, audit, publication etc.; 2. DG SANTE monitors the implementation of the action, e.g. through regular monitoring meetings at operational level; review of reported control results and any underlying management/audit reports (where applicable); 3. By the date stipulated in the contribution agreement, the organisation/agency submits the final technical and financial reports; 4. DG SANTE assesses the technical and financial reports and documents the results in checklists; 5. Payments follow DG SANTE's financial circuits with financial verifications, authorisations and encodings in SUMMA;	1.-2. All actions are monitored; 3.-4. All reports are assessed (technical and financial checklists completed; the control depth depends on risk criteria) 5. 100% of payments and SUMMA encodings 6. 100% if conditions are fulfilled	**Cost of control**: Estimated staff costs for monitoring and financial transactions; Mission costs for monitoring activities **Benefits of control:** Estimated value of the financial corrections made during ex-ante controls of the final payment; Benefit of "best value for money" is non-quantifiable as	-Time-to-pay ð Target: 100% on time -Rate of late interest or damage payments to total value of all procurement contracts ð Target: 0% -Files with relevance for OLAF adequately transmitted to OLAF and followed up ð Target: 100%

Contribution agreements with international organisations and decentralised agencies				
Main inherent risks	Mitigating controls	Control coverage	Costs and benefits of controls	Cost-Effectiveness indicators
	they are in the scope of the European Court of Auditors (ECA)'s annual financial audits; 6. If deemed necessary, the file is referred to OLAF (DG SANTE's SOPs apply).		quality aspects are impossible to quantify in an objective, meaning-ful and reliable way.	
Stage 4: Financial audits (ex-ante and ex-post) "on the spot"				
Main control objectives: (a) Detect and correct any error or fraud remaining undetected after standard ex-ante controls (legality & regularity; anti-fraud strategy); addressing systemic weaknesses in the ex-ante controls, based on the analysis of the findings (sound financial management); ensuring appropriate accounting of the recoveries to be made (reliability of reporting, safeguarding of assets and information); (b) Ensuring that the (audit) results from the ex-post controls lead to effective recoveries (legality & regularity; anti-fraud strategy); ensuring appropriate accounting of the recoveries made (reliability of reporting).				
Certain issues (errors or attempted fraud) cannot be detected and corrected during standard ex-ante desk controls; controls carried out in the form of **financial audits** (on-the-spot or remote) should -where deemed appropriate - complement the standard desk checks ([27]).	1. DG SANTE's financial audit strategy provides for financial audits on the spot of contribution agreements under condition that such audit activity would not overlap with audits of other DGs on the same international organisation, or the IAS/ECA on the decentralised agency; 2. DG SANTE follows up on audit recommendations linked to contribution agreements (other DGs, ECA or IAS); 3. Exceptions and internal control weaknesses are reported and analysed;	1. Risk based audit sample (no minimum audit coverage foreseen as some agreements might be excluded from audit by DG SANTE) 2. 100% of accepted recommendations implemented within the deadlines 3. 100% of financial procedures	**Cost of control**: Estimated staff costs for ex-post controls, internal audits and other supervisory controls Estimated mission costs for audits or other controls Cost of external audit services **Benefits of control:**	-Detected error rate ð Target: decreasing trend -Ratio of accepted audit recommendations (other DGs, Court of Auditors or IAS) implemented on time ð Target: 100% -Ratio of corrected control weaknesses to total detected weaknesses in procurement procedures ð Target: 100%

([27]) In 2024, DG SANTE did not perform any ex-post controls for contribution agreements..

Contribution agreements with international organisations and decentralised agencies				
Main inherent risks	Mitigating controls	Control coverage	Costs and benefits of controls	Cost-Effectiveness indicators
	4. If deemed necessary, the file is referred to OLAF (DG SANTE's SOPs on handling allegations and contacts with OLAF).	4. 100% if conditions are fulfilled	Value of the financial corrections made during ex-post audits or controls	-Average cost per audit to average amount of audit correction ð Target: > 100%
Detected **errors**, **irregularities** or **suspicions of fraud** should be addressed adequately and in a timely manner.	1. Systematic communication and registration of all audit results to management; 2. Financial and operational validation of recovery orders or payments following DG SANTE's financial circuit; 3. Exceptions and internal control weaknesses are reported and analysed; 4. Follow-up on audit recommendations on contribution agreements (other DGs, Court of Auditors or IAS)	1. 100% of final control results 2. 100% financial control of recovery orders 3. 100% of financial procedures 4. 100% of accepted recommendations implemented	**Cost of control**: Included in the estimated staff costs **Benefits of control:** Amount of actually corrected errors	-Audit results implemented ð Target: 100% -"Time to recover" from final accepted audit report to debit note ð Target: 100% "on time" -Ratio of accepted audit recommendations implemented on time ð Target: 90%

3. Subsidy payments to EU decentralised agencies

DG SANTE is responsible for five EU agencies. While one of these agencies is fully fee-financed (CPVO), DG SANTE pays annual subsidies from the EU budget to four agencies, including the European Chemicals Agency (ECHA) for its biocides activities (the lead responsible DG for ECHA is DG GROW).

Fully financed by the EU budget	Partially or fully fee-financed
- European Centre for Disease Prevention and Control (ECDC) - European Food Safety Authority (EFSA)	- European Medicines Agency (EMA) - European Chemicals Agency (ECHA) for its biocides activities - Community Plant Variety Office (CPVO)

Subsidy payments to EU decentralised agencies				
Main inherent risks	Mitigating controls	Control coverage	Costs/benefits of controls	Cost-Effectiveness indicators
Stage 1. "Mandate of the agency": founding regulation				
Main control objectives: ensuring that the legal framework for the management of the relevant funds is fully compliant and regular (legality & regularity), that the agency spends the money as intended (best value for public money, economy, efficiency), without any conflicts of interests (anti-fraud strategy)				
The **establishment (or amendment) of the mandate** of an EU agency should be free of any legal issues, as these could undermine the legal basis for the agency's	The legal framework of the EU agency is laid down in its founding regulation without expiry date. Amendments follow the Commission's legislative procedures and, since July 2012 the "Common Approach" ([28]) laid down by the Interinstitutional working group on EU agencies, e.g. - An impact assessment is carried out prior to establishing an EU agency and when amending its mandate;	**100% in-depth** once in establishment phase **100% in-depth** case by case if amendment or review is planned **Frequency:** When amendment or review of an agency's	**Cost of control**: Estimated SANTE staff costs involved in establishing an EU agency or the review or amendment of its founding regulation; Cost for external service contract for	Number of legal issues a/o negative opinions during interservice consultations ð Target: 0 Quality of the legal work not challenged by auditors or OLAF ð Target: 100%

([28]) http://europa.eu/about-eu/agencies/overhaul/index_en.htm.

Subsidy payments to EU decentralised agencies				
Main inherent risks	Mitigating controls	Control coverage	Costs/benefits of controls	Cost-Effectiveness indicators
management of the EU funds paid by DG SANTE to subsidise its running costs.	- Standard provisions including appropriate legal provisions are used as a reference point when a new agency is created or when existing founding acts are revised on a case by case basis; 1. In case of establishing an agency or amending its founding regulation, DG SANTE manages the interservice meetings/consultations; 2. DG SANTE also manages all subsequent procedural steps (Council, Parliament, etc.) towards the adoption of the regulation by the Council and the Parliament.	founding regulation is planned	impact assessments, etc. **Benefits:** The total annual budget amount paid as subsidy to the agency's running costs possibly at 100% if significant legal errors occurred.	
Stage 2. Assessment of the agency's control framework and financial rules				
Main control objectives: ensuring that the entrusted entity is fully prepared to start/continue implementing the delegated funds autonomously respecting the five control objectives set forth in the Financial Regulation: (i) legality and regularity, (ii) sound financial management, (iii) true and fair view reporting, (iv) safeguarding assets and information, (v) anti-fraud strategy				
The **financial and control framework** deployed by the EU agency should be fully mature to guarantee that the control objectives are met.	1. Implementing rules to the Staff Regulations (SR) adopted by the Commission apply by analogy to the agencies. The agency's Management Board, after having obtained the Commission's agreement, may decide to depart from these rules, not apply them or adopt rules on other subjects. DG SANTE, in co-operation with DG HR, consults and monitors; 2. The agency's Management Board adopts the financial regulation (FR) of the agency based on the Commission's "framework financial regulation" (FFR) for EU agencies; deviations from the FFR need the Commission's prior consent; DG SANTE, in co-	**100% in-depth** per agency as need be, e.g. if amendments are to be made **Frequency:** In 2018-2019 due to the new FFR and Internal Control Framework; Regular meetings of DG SANTE's inter-	**Cost of control:** Included in general estimate of SANTE's staff costs for monitoring and supervising the agency's activities **Benefits of control:** The total subsidy paid to the agency per year possibly at 100% if	EU agencies adopting their own control framework in compliance with the Commission's framework ð Target: all agencies EU agencies adopting their own rules of independence and conflict of interest compliant with the Commission's guidelines ð Target: all agencies

Subsidy payments to EU decentralised agencies				
Main inherent risks	Mitigating controls	Control coverage	Costs/benefits of controls	Cost-Effectiveness indicators
	operation with DG BUDG consults and monitors. All SANTE agencies have adopted in 2019 Financial Regulations which are in line with the Framework Financial Regulation ([29]); 3. Each agency adopts its rules of "independence" and "conflict of interest". DG SANTE actively monitors compliance with the Commission's guidelines on independence in DG SANTE's task force with the agencies and through bilateral contacts with the agencies. In addition to monitoring compliance, DG SANTE identifies and disseminates good practices in collaboration with the agencies.	agency task force on independence	significant legal errors occurred	
Stage 3: Operations: DG SANTE's monitoring and supervision ("control with the EU agency")				
Main control objectives: ensuring that DG SANTE is fully and timely informed of any relevant management issues encountered by the agency, in order to possibly mitigate any potential financial and/or reputational impacts				
DG SANTE should be informed timely of relevant **management issues** encountered by the EU agency**;** DG SANTE should react upon	1. DG SANTE's coordinating Unit ensures a coherent approach towards all agencies and exchange of good practises following the "guidance paper on relations with decentralised agencies" (since 2017); the Commission guidelines for the programming document and the template for the activity report are applicable; 2. Regular bilateral meetings with the agencies take place with the aim to ensure efficient exchange	**Coverage**: all of the agency's activities are monitored and supervised **Depth** of control: risk based; if need be, DG SANTE has access to the agency's internal control information	**Cost of control**: Included in the general estimate of DG SANTE's staff costs for monitoring and supervising the agency's activities; Mission costs for monitoring activities	Regular meetings between the agency and DG SANTE at management and technical level ð Target: to be defined with each agency Management Board meetings with DG SANTE participation

([29]) The CPVO as fully self-financed agency is not bound by the FFR, but aligned its 2019 financial rules largely with the FFR. The deviations were consulted with the Commission and the Court of Auditors.

Subsidy payments to EU decentralised agencies				
Main inherent risks	Mitigating controls	Control coverage	Costs/benefits of controls	Cost-Effectiveness indicators
notified issues timely and adequately; if not, this could reflect negatively on the Commission's reputation.	of information and good co-operation at the level of (i) operational and financial Units and (ii) Directors/DDG/DG. In addition, DG SANTE regularly convenes meetings bringing together all Heads of its partner agencies and DG SANTE management; 3. The Management Board (MB) of an EU agency meets about 4 times a year with participation of DG SANTE; it adopts the agency's Single Programming Document (SPD, combining multiannual and annual strategic and resource programming) as well as "strategy documents", e.g. on independence. DG SANTE comments through the MB and prepares a formal Commission Opinion on the SPD; 4. The agency reports to its MB (DG SANTE being a member) on the achievement of objectives, budget implementation and all other important issues relating to operational and financial management and internal audit; in addition, if applicable, DG SANTE participates in the agency's Audit Committee meetings; 5. The "Template for Consolidated Annual Activity Report" for decentralised agencies foresees that the agencies report on the "Assessment of the effectiveness of the internal control systems". All SANTE agencies that receive a Union subsidy adhere to this template. DG SANTE monitors that the information is provided and assesses;	**Frequency**: depending on legal obligations of the agency (e.g. n° of MB meetings per year); working relations established with DG SANTE; in addition, on special request or in specific cases	**Benefits of control:** The total subsidy paid to the agency per year possibly at 100% if significant legal errors occurred	ð Target: depends on the agency (about 3 to 4 times per year) Relevance and reliability of control data reported by the agency ð Target: qualitative analysis done for the document sent to the Management Board

Subsidy payments to EU decentralised agencies				
Main inherent risks	Mitigating controls	Control coverage	Costs/benefits of controls	Cost-Effectiveness indicators
	6. After adoption by the MB, the agency publishes its annual report, final accounts and report on financial management; 7. If need be, DG SANTE informs the Internal Audit Service (IAS), refers issues to OLAF or as member of the MB triggers the "warning system" (SG note to all DGs Ref. Ares(2013)231088 - 21/02/2013).			
Stage 4: Audit and evaluation, discharge				
Main control objectives: ensuring that independent sources provide DG SANTE with information which may confirm or contradict the management reporting received from the agencies themselves				
DG SANTE should get **sufficient information** from independent sources on the EU agency's **management achievements** to draw conclusions on the assurance for the subsidies paid to the agency; if not, this might reflect negatively on the Commission's reputation.	1. The Internal Audit Service of the Commission (IAS) is the internal auditor of EU agencies and has the same rights and obligations towards EU agencies as towards the Commission (exception: the fully fee financed CPVO); 2. Every year, the European Court of Auditors (ECA) audits the accounts and transactions of the agency and issues a declaration of assurance; in addition, the ECA issues Special Reports on agencies; DG SANTE monitors the agency's follow-up on the Court's recommendations; 3. Every year, the agency undergoes the discharge procedure; DG SANTE monitors the agency's follow-up on the recommendations made by the discharge authorities; 4. Founding regulations foresee regular external evaluations of the agencies: - EMA every 10 years (last completed in 2021);	**Coverage**: 100% of the agency's activities audited and evaluated **Depth** of control: risk based; auditors have full access to the agency's internal control information **Frequency**: Regularly by the IAS Annually by the Court of Auditors Frequency of external evaluations varies with the agencies	**Cost of control**: Included in the general estimate of SANTE's staff costs for monitoring and supervising the agency's activities **Benefits of control:** The total amount of the subsidy paid to the agency per year possibly at 100% if significant legal errors occurred	DG SANTE's analysis of critical and very important audit findings of internal and external auditors and the agency's implementation of the audit findings ð Target: all analysed and discussed Court of Auditors' assurance on the accounts and operating budget ð Target: positive assurance ð Target: all recommendations implemented Discharge authorities grant discharge to the agency ð Target: discharge granted

Subsidy payments to EU decentralised agencies				
Main inherent risks	Mitigating controls	Control coverage	Costs/benefits of controls	Cost-Effectiveness indicators
	- EFSA every 6 years (last completed 2018); - ECDC every 5 years (last completed 2019). DG SANTE participates in the Steering Committee and Technical Evaluation Committee; 5. Through its representation in the agency's Management Boards and Audit Committees, DG SANTE encourages that evaluation reports and audit reports are timely sent to DG SANTE and that adequate actions are defined and timely implemented by the agency to address the issues identified in those reports.			ð Target: all recommendations of the discharge authorities implemented External evaluation concluding positively on the agency's activities
Stage 5: DG SANTE's payments of the subsidy				
Main control objectives: ensuring that DG SANTE fully assesses the management situation at the EU agency, before either paying out the (next) instalment of the subsidy to the agency or deciding to cut, suspend or interrupt the (next) payment (legality & regularity, sound financial management, anti-fraud strategy)				
DG SANTE might not be aware of management issues that could lead to financial and/or reputational damage for the Commission as it pays the subsidy to the agency.	1. On the basis of the agency's annual budget and work programme adopted by the Management Board, DG SANTE pays the subsidy to the agency's administrative budget in several instalments: - An instalment is paid in year N on request of the agency based on a cash forecast; - Prior to the subsidy payment, financial checks are carried out according to DG SANTE's financial circuits with financial verifications, authorisations and encodings in SUMMA; 2. All instalments remain pre-financing payments until the agency's accounts have been audited by	**Coverage**: 100% of DG SANTE's subsidy payments through the established financial circuits **Depth** of control: risk based **Frequency**: Administrative budget of the agency annually audited by the Court of Auditors	**Cost of control**: Estimated staff costs for budget and finance in central financial Unit **Benefits of control:** The total subsidy paid to the agency per year possibly at 100% if significant legal errors occurred	Number of reported monitoring issues, incidences of payment suspensions or reductions and/or exception reports relative to DG SANTE's subsidy payment to the agency ð Target: qualitative analysis of reasons for the reported issues; all issues adequately followed up Ratio of recovery of the positive budgetary outturn of year N on subsidy paid in year N-1

Subsidy payments to EU decentralised agencies				
Main inherent risks	Mitigating controls	Control coverage	Costs/benefits of controls	Cost-Effectiveness indicators
	the European Court of Auditors and the agency has submitted its final accounts (in general by July N+1); 3. On the basis of the agency's final accounts, DG SANTE clears all pre-financing payments in year N+1 and, if applicable, recovers unspent amounts of the instalments paid to the agency; no additional payment is made.			Files with relevance for OLAF adequately transmitted to OLAF and followed up ð Target: 100% Time-to-pay (target: maximum 30 days) ð Target: 100% on time

ANNEX 7: Specific annexes related to "financial management"

7.1 Effectiveness of controls

7.1.1. Legality and regularity of the transactions

DG SANTE has set up internal control processes aimed to ensure the adequate management of the risks relating to the legality and regularity of the underlying transactions, considering the annual character of programmes as well as the nature of the payments concerned.

Table 7.1 Overview table of DG SANTE's budget implementation - payments made in 2025

DG SANTE - payments made in 2025 (in M€)							
Management mode	Direct management			Indirect management		Total	
Risk type / Activities	Grants	Procurements	Budget transfer to HaDEA	Contribution agreements	Subsidy payments to agencies		
EU4Health		41.9	244.4	26.0		**312.3**	31.6%
SMP Food Strand	130.8	23.8	141.4	5.6		**301.6**	30.6%
Administrative expenditure		6.1				**6.1**	0.6%
Other policies*		5.1				**5.1**	0.5%
HaDEA**					62.2	**62.2**	6.3%
ECDC					93.3	**93.3**	9.5%
EFSA					150.9	**150.9**	15.3%
EMA					48.9	**48.9**	5.0%
ECHA-biocides					6.8	**6.8**	0.7%
Total (including HaDEA)	**130.8**	**76.8**	**385.8**	**31.6**	**362.2**	**987.3**	**100%**
Total (excluding HaDEA as in Annex 3)	**130.8**	**76.8**		**31.6**	**362.2**	**601.5**	
EC balance sheet category							***M€***
Intangible Assets - internally generated IT software							***44.6***
Inventories of antigen stocks for animal diseases							***13.6***

ad *: Co-delegations received from other DGs
ad **: Subsidy payments to HaDEA are direct management, including EUR 35,8 million co-delegations from other DGs

In the policy area Food Safety, DG SANTE follows an integrated approach with the aim to ensure a high level of food safety, animal health, animal welfare and plant health within the European Union through coherent farm-to-fork measures and adequate monitoring. Applicable as from 1 January 2021, the SMP ([30]) – Food Chain strand is the main basis for the corresponding expenditure. The SMP does not affect the continuation or modification of actions initiated under the previous legislation ([31]).

([30]) Regulation (EU) 2021/690 of the European Parliament and of the Council of 28/04/2021 on the Single Market Programme (SMP) and repealing – inter alia - Regulation (EU) No 652/2014 the Common Financial Framework (CFF); 2021 work programme C(2021)3046 of 06/05/2021 and 2022 work programme C(2022)724 of 17/02/2022 last amended by C(2022)9176 of 07/12/2022.
([31]) Regulation (EU) No 652/2014 of the European Parliament and of the Council of 15 May 2014.

In 2025, administrative expenses related to salaries and/or missions are reported by the service responsible for the commitment, although the payments were executed by another service, notably the PMO and/or DG HR ([32]), which, until 2024, also reported the corresponding expenditure. This new reporting arrangement was introduced in the context of data rationalisation linked to the implementation of the Commission's new IT accounting system. In 2025, these expenses represented 0.7% of DG SANTE's total payments.

Table 7.2 Food Safety Grants

Payment credits implemented by DG SANTE *(without HaDEA) ([33])*	**2025 M€**	**2024 M€**
Veterinary emergency fund and Closure of previous veterinary programmes (grants to Member States)	**130.8**	**135.2**
Phytosanitary emergency measures (grants to Member States)	**0.05**	**5**
Grants to international organisations under direct management (indirect management is included in part 7.1.1.3 below and in annex 11)		**0.3**
Total grants	**130.8**	**140.5**

Following the transfer of budget implementation tasks to the Health and Digital Executive Agency (HaDEA) in 2021 (see annex 7.1.1.3 below), the grant management of the animal and plant disease eradication programmes of the Member States, the grants for European Reference Laboratories and Centres (EURL and EURC) and the grants for Member States' control plans monitoring antimicrobial resistance (AMR) are implemented by the agency.

DG SANTE still manages the grant agreements with Member States for their veterinary and plant emergency measures and grants to international organisations such as the UPOV (International Union for the Protection of New Varieties of Plants), FAO (Food and Agriculture Organization) and WOAH (World Organisation for Animal Health).

- Veterinary emergency measures: in 2025, a total of 34 grant agreements were signed with Member States for cost reimbursements in relation to veterinary emergency measures taken in 2022 and 2023 to combat, first and foremost,
    - Avian Influenza: 18 grant agreements for a total value of EUR 160.9 million for which pre-financing payments of EUR 90.46 million were made.
    - African Swine Fever: 10 grant agreements for a total value of EUR 12.95 million for which pre-financing payments of EUR 6.84 million were made.
    - Newcastle Disease: 3 grant agreements for a total value of EUR 0.28 million for which prefinancing payments of EUR 0.137 million were made.

([32]) Type III co-delegation.
([33]) Without credits co-delegated to other DGs.

- Sheep and goat pox: 3 grant agreements for a total value of EUR 3.4 million for which prefinancing payments of EUR 2.7 million were made.

- Addressing the combat of organisms harmful to plants, 2 grant agreements for a total value of EUR 0.09 million were signed covering 2023 measures against the Clavibacter Sepedonicus, Ralstonia Solanacearum and Melgmy plant pests.

The control process of DG SANTE's grant management pertaining to the Member States' emergency measures is divided into four distinct stages, each with specific control objectives. The description focuses on the veterinary and phytosanitary emergency measures as they account for the majority of the grants in the Food Safety policy area (see table 7.1 above). As unforeseeable developments in emergency situations entail a relatively high uncertainty of whether or not a measure is eligible, DG SANTE focusses its control efforts on ex-ante checks in the form of financial audit on the sport or remote before the final payment is made.

Stage 1: Legal base and Member States' submission of applications

The SMP-Food Chain strand provides for the award of grants to Member States and third countries in case of emergency measures taken as a result of a confirmed occurrence of a number of listed diseases in accordance with Regulation (EU) 2016/429 for animal diseases and Regulation (EU) 2016/2031 for plant pests. Member States provide DG SANTE with preliminary information on the ongoing and planned actions, on the estimated total eligible costs (as defined in the SMP, annex I) and on the expected completion date of the emergency measures.

At the first stage, key controls are mostly directive and preventive: application guidelines for the Member States; assessment of the technical quality and financial analysis of the application and its regular updates.

The award criteria for the financial contribution are fixed in the SMP (a) compliance with the requirements of the relevant Union law; (b) relevance of the planned activities in view of the prevention or eradication of the animal diseases and plant pests; (c) activities related to prevention or eradication of plant pests during the first year after the detection of the outbreak.

In addition, the SMP, Article 13, provides for derogations from the principle of non-retroactivity pursuant to Article 196 of the Financial Regulation as follows:

- Emergency measures are eligible prior to the date of submission of the grant application in accordance with Article 196(2), second subparagraph, point (b) of the Financial Regulation ([34]);
- Emergency measures are eligible from the date of the suspected occurrence of an animal disease or the presence of a plant pest, provided that this occurrence or presence is subsequently confirmed.

([34]) SMP Art. 13(1) as in previous legislation.

Stage 2: Approving the emergency measure and signing the grant agreement

In 2025, DG SANTE evaluated 36 grant applications for veterinary emergency measures that Member States had taken in 2021 and 2023. Having taken the award decision, the authorising officer by sub-delegation signed the corresponding grant agreements. The grant agreements were adapted ([35]) to the novelties of the Single Market Programme (SMP 2021-2027) and further to an audit recommendation made by the IAS to improve certain grant agreement provisions.

The signed grant agreements were not preceded by a budgetary commitment by way of derogation from Article 111(2) of the Financial Regulation: according to the SMP, Article 4(5), the Commission makes the budgetary commitment for the grant awarded for veterinary and phytosanitary emergency measures after the payment applications submitted by Member States have been assessed.

Stage 3: Managing financial transactions and ex-ante controls

Following the signature of the 34 agreements for veterinary emergency measures, DG SANTE made pre-financing payments for a total of EUR 100.1 million which corresponded to between 0-80% of the co-financing amount.

DG SANTE's assessment of the final payment applications in the form of cost claims of the Member States followed the internal control strategy for emergency files. Each cost claim was assessed (technical and financial checks) based on a risk analysis. The controls took place prior to the processing of financial transactions by the operational and financial actors involved in DG SANTE's financial circuit: centralised financial cell with operational verification in the policy Units and authorising officer by sub-delegation for commitments and payments at the level of the Deputy Director-General for Food Sustainability. The aim was to detect and correct errors before authorisation of a financial operation.

In addition, a risk-based sample of payment applications was subject to an ex-ante financial control in the form of an audit in the Member State. Audits in 2025 took place on the spot. About 70% of all final payments were preceded by a financial audit. The audit results in 2025 show a weighted average correction rate of around 8.3%. All corrections were done prior to the final payment. DG SANTE made the following main observations: (a) the Member States faced difficulties to understand some of the eligibility criteria or did not apply them correctly; (b) in several cases, Member States lacked sufficiently detailed data to evidence the costs in their claim as contracts with suppliers rarely include clauses for the provision of details on the work performed; (c) with regard to compensation for the animals culled, an over-evaluation was noticed when animals were compensated based on experts' evaluations rather than pre-defined value scales.

([35]) The IAS made an audit recommendation to improve the grant agreement provisions and the unit cost methodology. The action plan has been implemented by late 2022 (see Annex 8.1.2 below).

Table 7.3 Indicators for grants for emergency measures at control stage 3

Indicators	*Targets*	2025	2024
Stage 3: Monitoring and financial management			
Member States' applications analysed before payment	*100%*	100%	100%
Number of registered **"exception reports"** related to veterinary and phytosanitary emergency measures	*n/a*	0	0
Instances of Article 93 FR ([36])	*n/a*	0	0
Late interest payments relative to total value of grants (since 2020 no more case)	*0%*	0%	0%
Ex-ante controls in the form of financial audits **Audit coverage**	*< 50%*	70%	70%
Ex-ante controls in the form of financial audits **Average corrections** - Veterinary emergency fund - Phytosanitary emergency fund	*n/a*	 6.8% 18.5%	 14% 5%

No "exception report" was submitted in 2025 pertaining to veterinary and phytosanitary emergency measures. The systematic registration of so-called "exceptions" and internal control weaknesses is a supervisory tool to improve the functioning of the internal control system. The underlying causes behind these exceptions and weaknesses were analysed and reported in an overview table.

Stage 4: Managing "on-the-spot" controls and error corrections for grants

Since the transfer of budget implementation tasks, including ex-post controls, to HaDEA in 2021, DG SANTE has not carried out ex-post controls anymore on the transferred grants. The last batch of previous audits in the policy area Food Safety was closed in 2022. Therefore, 2025 is the third year for which DG SANTE does not report on an error rate of ex-post controls anymore.

Table 7.4 Indicators for grants at control stage 4

Indicators	*Target*	2025	2024
Stage 4: Ex-post controls			
Ex-post control **detected error rate** (policy area Food Safety)	*n/a*	n/a*	n/a*
Ex-post control **residual error rate** (policy area Food Safety) (Without one exceptional file)	***< 2,0%***	n/a*	n/a*
Estimated error rate as no ex-post error rate is available	***< 2,0%***	2,0%	2,0%
Amount of net financial corrections identified in year N compared with amount of transactions audited	*n/a*	*n/a**	*n/a**
Financial corrections in year N linked to ex-post audits finalised in year N (until 31/12/year N)	*n/a*	*n/a**	*n/a**

([36]) Article 93 of the FR(2024) on the treatment of financial irregularities.

Indicators	*Target*	2025	2024
Total financial correction of detected errors by mid-March 2026	*n/a*	*n/a**	*n/a**

Ad *: Files transferred to HaDEA

Ad **: Errors of an exceptionally small sample; no extrapolation possible

Instead, DG SANTE's internal control strategy provides for extensive ex-ante controls on the type of grants that is still managed by DG SANTE: Member States' cost claims for emergency measures. There is a risk that not all errors are detected and corrected during ex-ante controls at the desk; thus, DG SANTE complements its desk checks by financial audits either on-the-spot in the Member States or carried out remotely. Preference is given to audits that take place prior to the final payment (ex-ante) rather than after the final payment (ex-post) for the following reason: despite clear eligibility rules and guidelines for Member States, there is a relatively high uncertainty of whether or not a measure is eligible given the many unforeseeable developments that emergency situations typically entail. Consequently, errors in cost claims can be detected early on and corrected prior to the final payments.

Ex-ante financial audits are carried out on a sample basis. The audit samples are taken based on a risk analysis rather than following a statistical random selection. The risk-based approach is considered more cost-effective given the heterogeneity and relatively small size of DG SANTE's audit population. A key indicator is the correction rate, calculated as an average error rate from the audited sample.

As all errors are corrected before the final payment and given the high coverage of ex-ante audits (about 70% in 2025), the residual error rate is estimated at just under 2%.

Based on this experience, DG SANTE does not consider it appropriate to make a reservation in the Director-General's 2025 declaration of assurance.

7.1.1.2 Procurement

The following paragraphs describe the provisions for the management of public procurement in the policy areas Food and Feed Safety ([37]) and Public Health ([38]) within the remit of DG SANTE.

About 78% of the 2025 payment budget of the EU4Health Programme was implemented by the Health and Digital Executive Agency (HaDEA). The remaining 22 % was implemented by DG SANTE mainly through contribution agreements with international organisations under indirect management and public procurement procedures (e.g. specific contracts on framework contracts for IT services, communication, evaluation and impact assessments and administrative arrangements with JRC).

([37]) Regulation (EU) 2021/690 of 28 April 2021 – SMP; C(2021)3046 of 6 May 2021 – work programme 2021-2022 for the food chain strand of the SMP.

([38]) Regulation (EU)2021/522 of 24 March 2021 – EU4Health Programme; C(2024) 7871 final of 15 November amended EU4Health Work Programme.

Table 7.5 Procurement DG SANTE

Commitment credits implemented by DG SANTE *(without HaDEA)* [39]	**2025 M€**	**2024 M€**
Food and Feed Safety: DG SANTE procurement expenditure	**23.8**	**30**
Health Programmes implemented directly by DG SANTE	**41.9**	**34.9**
Procurement other policy areas (operational credits mainly)	**5**	**1.8**
Building expenditure Ireland and other administrative credits	**6.1**	**2.3**
Total budget implemented	**76.8**	**68.1**

The control process for public procurement is divided into three distinct stages, each with specific control objectives as described below.

Stage 1: Assessing procurement needs and selecting the offer

DG SANTE starts planning a procurement procedure by assessing the procurement needs when preparing the annual work programmes in each policy area. With regard to the choice of the right procurement procedure, the most important criteria are the estimated total value of the contract and the type of service/supply needed.

With a view to achieving a good quality of the tender documents, harmonisation and efficiency gains, since mid-2014 DG SANTE has centralised the management of public procurement procedures. The centralisation covers new procurement procedures the value of which is above EUR 15 000 and the specific contracts under Framework Contracts with re-opening of competition. The central team also gives support to all procedures involving pilot projects and preparatory actions, be it through public procurement or through grants. In 2025, some exceptions to the centralisation still existed for organisational/technical or geographical reasons. These concerned mainly: local calls for tenders managed by and for DG SANTE's site located in Grange, Ireland (Grange); specific contracts under Framework contracts for communication-related activities managed by the Communication Unit; specific contracts under Framework contracts for IT procurement procedures managed by DG SANTE IT Unit.

Striving to reduce administrative burden, DG SANTE published calls above the Directive threshold (in 2025, EUR 143 000) through the eProcurement tools of the Commission which include: Public Procurement Management Tool (PPMT) - it supports the planning, preparation, launch and monitoring of all types of procurement procedures under the Financial Regulation; the EU Funding & tenders Portal (F&T Portal), which is the entry point for all participants; eSubmission for offers submission; as well as My Workplace for launching specific request for services under Framework Contracts and supporting contracts implementation.

Main open, negotiated and restricted procedures

Through open calls for tenders, DG SANTE signed a framework contract for Provision of online testing tools for eHealth services" (EUR 0.7 million), procured vaccine against Sheep Pox (EUR

[39] Without credits co-delegated to other DGs or transferred to HaDEA.

0.403 million), procured a study to support the rapid assessment of policy scenarios to strengthen innovation and competitiveness in the field of biotechnology in the EU (EUR 0.62 million).

In addition, in 2025 DG SANTE launched and awarded an interinstitutional call for tenders with HaDEA and EFSA for the total estimated value of EUR 30 million for the “Provision of services in the areas of evaluation, impact assessment, monitoring of implementation and other related services in relation to health and food policies”. This is one of the most crucial services in DG SANTE, however it does not entail any budgetary commitment.

Most procurement activities of DG SANTE office in Grange concern very low and low value procedures (below EUR 60 000) related to the day-to-day running and maintenance of the site in Grange. This is because the office is managed by DG SANTE and not by OIB or OIL. The office also carried out a negotiated procedure for works concluded with a framework contract for the renovation of the external building cladding (EUR 1.4 million) and a negotiated procedure for the supply of heating oil (EUR 65 000). In addition to the type of calls for tenders above mentioned, in 2025, as in previous years, DG SANTE made extensive use of framework contracts concluded by itself or by other DGs (mainly DGs DIGIT and COMM) and also through negotiated procedures which value is below 60 000 euro. More than 100 of specific contracts under FWC were awarded in 2025.

The share of different procedures above 60 000 awarded thus fluctuates significantly from year to year: in 2025 about 54% of the total contract value was awarded through the negotiated procedures.

The main reasons for using negotiated procedures are that DG SANTE often needs services in specialised fields with only one or two suitable providers, especially for site management of the office building in Grange, Ireland.

Public Procurement Committee (PPC)

Procurement procedures (open calls for tender and negotiated procedures) for contracts above the Directive threshold (EUR 143 000 in 2025) are examined by DG SANTE’s "Public Procurement Committee". The committee is designed as an ex-ante control prior to signature of an award decision by an authorising officer by sub-delegation (AOSD). It gives an opinion on the compliance with Commission rules and procedures for public procurement, including the use of adequate contractual provisions. The Committee consists of representatives of the central financial cell, the decentralised financial cells and the legal affairs Unit.

Table 7.7 Indicators for procurement at stage 1

Indicators	*Targets*	2025	2024
Stage 1: Assessing procurement needs and selecting the offer			
Rate of open calls for tenders for which - No offer was received (in 2025: 0 out of 3, in 2024: 1 out of 2) - The procedure had to be cancelled (in 2025: 0 out of 3, in 2024: 0 out of 1)	*0%* *0%*	**0%** **0%**	**50%** **0%**
Rate of negotiated procedures ([40]) for which - No offer was received - The procedure had to be cancelled	*0%* *0%*	**0%**	**0%** **0%**
Number of procurement procedures within the scope of the PPC	*n/a*	**4**	**4**
Number of procurement procedures examined by the PPC	*n/a*	**4 ([41])**	**3**
% of procurement procedures examined by PPC	*100%*	**100%**	**100%**
Ratio of positive opinions of the Public Procurement Committee	*n/a*	**100%**	**N/A**
Public Procurement Committee opinions followed by the authorising officers responsible	*100%*	**N/A**	**N/A**

In 2025, the Public Procurement Committee (PPC) provided five positive opinions on procurement contracts with a total maximum value EUR 33.1 million ([42]).

Stage 2: Monitoring the implementation of procurement contracts and managing financial transactions

The second stage of control procedures for procurement concerns the technical and financial monitoring of the implementation of the contracts. This is the responsibility of the operational Units and thus is not part of the centralisation of the procurement procedures. The frequency and depth of the controls depend on the size, complexity and sensitivity of the contract.

The objective is, firstly, to ensure that the contractor meets the objectives, delivers good quality, on time, and complies with the contract provisions. Secondly, DG SANTE aims to detect and correct errors before a financial operation is authorised. The financial circuits provide for a verification of each financial transaction by the responsible financial Unit. Checks are done at the desk prior to the authorisation of the transaction (ex-ante).

([40]) Procurement procedures above EUR 60 000.

([41]) The PPC also examined one middle value negotiated call for tenders for works contract for Grange for "Remedial works to external timber cladding and high-level joinery at the European Commission buildings in Grange, Dunsany, Co. Meath, Ireland" of the value awarded of EUR 1.4 million.

([42]) The total estimated maximum value of the procedures analysed – amount awarded - including Grange - is EUR 32.7 million.

Table 7.8 Indicators for procurement at stage 2

Indicators	*Targets*	2025	2024
Stage 2: Monitoring of contract implementation financial management			
Late interest payments relative to total amount of payments made for procurement (in 2025: 18 cases for a total of €44 407.19)	*0%*	**0.07%**	0.0%

Stage 3: Supervisory measures

In order to measure the effectiveness of ex-ante controls, DG SANTE has established diverse supervisory measures such as the reporting on exceptions and non-compliance events, defined as control over-rides or deviations from policies and procedures, and the results of other supervisory activities. In addition, DG SANTE's procurement procedures can be audited by the Court of Auditors and the IAS.

Ex-post controls on procurement contracts at the contractor's site are conducted only in exceptional cases when high risks have been identified during ex-ante controls. In 2025, no such audit was conducted. DG SANTE considers that adequate procurement procedures ensuring a good price-quality ratio as well as the technical and financial checks prior to payment are sufficient to give reasonable assurance that error rates are very low. Therefore, DG SANTE believes, there is little added value to carry out ex-post controls of payments linked to procurement on a systematic basis.

Table 7.9 Indicators for procurement at stage 3

Indicators	*Targets*	2025	2024
Stage 3: Supervisory measures			
Number of registered **"exception reports"** relative to procurement procedures	*n/a*	**2**	**11**
Instances of Article 93 FR ([43])	*n/a*	**0**	**0**
Ex-post control in the form of financial audits (on-the-spot or remote): detected error rate in a procurement contract	*< 2%*	**n/a**	**n/a**
Recovery orders of year N: (in number) in amount	*n/a*	**(1)** 0.02 M€	**(4)** 8.4 M€
For procurement: **Ombudsman** cases or legal proceedings opened in year N	*n/a*	**0**	**1**

The systematic registration of so-called "exceptions" and internal control weaknesses is a supervisory tool to improve the functioning of the internal control system. The underlying causes behind these exceptions and weaknesses were analysed and brought to the attention

([43]) Article 93 of the FR (2024) on the treatment of financial irregularities.

of the Director-General. Two "exception reports" of 2025 pertain to a derogation from the Financial Regulation or a breach of existing regulatory and/or contractual provisions. In both cases, specific Contract end date fell after the maximum end date for implementation of specific contracts under the relevant Framework Contract. DG SANTE assesses that these derogations have no bearing on the Director-General's declaration of assurance as they did not point to significant weaknesses in the internal control procedures and – where appropriate – corrective actions were taken immediately (for more detail on "exception reports" see Annex 8.2).

DG SANTE issued in 2025 one recovery order related to public procurement for a value of EUR 2 533 for recovering an amount not due.

In 2025, no Ombudsman case relevant for DG SANTE's procurement procedures was opened.

7.1.1.3 Contribution agreements under indirect management

Carrying out actions of the 2023, 2024 and 2025 work programmes of the EU4Health programme and the SMP, in 2025, DG SANTE concluded contribution agreements with international organisations and made mostly pre-financing payments of EUR 26.9 million (Annex 11).

DG SANTE also concluded contribution agreements with EU decentralised agencies with the European Medicines Agency (EMA) for a pilot of electronic product information (ePI) and with the European Centre for Disease Prevention and Control (ECDC) for the reinforcement of the vaccination information portal and for improving and strengthening the EU early warning and response system and national alert and information systems (EWRS). A contribution agreement with the European Chemicals Agency (ECHA) was signed on serious cross-border threat to carry out and deliver public health risk assessments on chemical incidents.

Table 7.10 Contribution agreements with EU decentralised agencies

Programme	EU decentralised agency	2025 Payments in M€	2024 Payments in M€
EU4Health	EMA	2.4	1.5
	ECDC	1.2	5.7
	ECHA	-	0.5
Total		**3.6**	7.7

Stage 1 Prior to contracting: ex-ante (re)assessment of the international organisation's financial and control framework

The organisations were all pillar assessed, i.e. they demonstrated a level of financial management and protection of the EU financial interest equivalent to that of the Commission. This is verified by an ex-ante assessment ("pillar assessment") of the entity, carried out by

the Commission. DG SANTE does not conduct own pillar assessments itself but relies on assessments conducted by other DGs.

Pillars are the broad areas covered by this assessment. According to the Financial Regulation (2024) and the pillar assessment methodology adopted on 17 April 2019, these are:

- Basic pillars (compulsory): (1) internal control, (2) accounting, (3) independent external audit;
- Operational pillars (optional): (4) grants (including certain aspects from the discontinued sub-delegation pillar), (5) procurement, (6) financial instruments and budgetary guarantees;
- New pillars (compulsory): (7) exclusion from access to funding, (8) publication of information on recipients, (9) protection of personal data.

Stages 2 and 3: "Contracting" and monitoring the international organisation's implementation of the contribution agreement

The needs for contribution agreements with international organisations are identified during the preparation of the annual work programmes for the EU4Health and SMP. After having evaluated the proposals, DG SANTE used the corporate template for all its contribution agreements with international organisations.

Table 7.11 Indicators for contribution agreements stage 3

Indicators	***Targets***	**2025**	**2024**
Stage 3: Monitoring			
Number of registered **"exception reports"** relative to the contribution agreements	*n/a*	**1**	2

One "exception report" of 2025 relating to the contribution agreements pertain to a derogation on managing credits not complying with the principle of annuality and in particular with Art. 12.1 of the Financial Regulation. DG SANTE assesses that this derogation has no bearing on the Director-General's declaration of assurance as it did not point to weaknesses in DG SANTE's internal control procedures.

7.1.1.4 Budget implementation tasks entrusted to other services and entities

DG SANTE has entrusted parts of its budget for implementation in direct management by the executive agency HaDEA. In addition, DG SANTE contributes to the operating budget of HaDEA.

DG SANTE's supervision arrangements are based on the principle of controlling 'with' the relevant entity. For details, see Annex 6 (relevant internal control system).

Health and Digital Executive Agency (HaDEA)

The control process is divided into three distinct stages, each with specific control objectives (for more detail see Annex 6).

Stages 1 and 2: Mandate of the agency and readiness assessment of its control framework towards autonomy

The European Health and Digital Executive Agency (HaDEA) was established from 16 February 2021 until 31 December 2028 ([44]). It is entrusted with the implementation of the following (parts of) Union programmes:

Table 7.12 Union programmes delegated to HaDEA

Parent DGs	Programme
SANTE and HERA	EU4Health programme ([45])
SANTE	Single Market Programme ([46]): Food chain strand
RTD, CNECT	Horizon Europe: Pillar II, Cluster 1: Health
RTD, CNECT, GROW, DEFIS	Horizon Europe: Pillar II, Cluster 4: Digital, industry and space
CNECT	Digital Europe Programme
CNECT	Connecting Europe Facility: Digital

DG SANTE pays a subsidy to HaDEA to cover its running costs (administrative or operating expenditure) for the implementation of the tasks transferred to it. The other parent DGs also pay their share of the total costs to implement the transferred tasks related to their programmes.

HaDEA is subject to an individual discharge procedure by the European Parliament for the implementation of its own budget (administrative expenditure). The operational budget implemented by the agency stems from the Commission budget and is part of the general discharge given to the Commission.

The use made of the subsidy is audited – inter alia – by the European Court of Auditors.

([44]) Commission Implementing Decision (EU) 2021/173 of 12 February 2021.
([45]) Regulation (EU)2021/522 of 24 March 2021 – EU4Health Programme.
([46]) Regulation (EU) 2021/690 of 28 April 2021 – SMP.

Table 7.13 Subsidies paid by DG SANTE to HaDEA

HaDEA	2025 M€	2024 M€
Subsidy payments for administrative budget (SANTE share)	**57.5**	**19.3**
Subsidy payments for administrative budget (Delegated share of other parent DGs)	***35.8***	***36.2***
Operational budget transferred from SANTE to HaDEA ➢ Payments made under EU4Health ➢ Payments made under the SMP	 **244.3** **141.4**	 **255.9** **79.8**

Since its establishment in February 2021, HaDEA set up its internal control framework and reached full autonomy with the appointment of its Director nominated by the Commission on 21 January 2022, with effect from 16 February 2022.

Stage 3: DG SANTE's monitoring and supervision ("control with the executive agency")

According to HaDEA's Act of delegation ([47]), DG SANTE is the lead parent Directorate-General and has specific responsibilities in relation with the monitoring and supervision of horizontal issues in the agency.

DG SANTE supervises the activities of the agency and carries out supporting and steering activities, in particular through the meetings of the Steering Committee, which are chaired by DG SANTE's Deputy Director-General (responsible for Health). The Steering Committee is responsible for the adoption of the agency's annual work programme and administrative budget, including the establishment plan. The agency informs the Steering Committee on the achievements of its objectives, audit findings and relevant follow-up, as well as of any other important issue relating to internal control, financial management and audit. Furthermore, regular bilateral meetings at the level of the Units concerned in DG SANTE and HaDEA ensure the necessary co-ordination of activities.

As a key document to govern the day-to-day interactions between the agency and its parent DGs, the Memorandum of Understanding (MoU), signed on 21 December 2021, covers general provisions and modalities regarding mainly IT governance, supervision, HR, planning, reporting and evaluation. In addition, DG SANTE and HaDEA signed the specific Memorandum of Understanding for the implementation of the EU4Health programme on 13 December 2022 and the Memorandum of Understanding for the SMP Food chain strand on 16 February 2023.

DG SANTE follows up on the agency's consumption of both the administrative and the operational budget. In 2025, no serious control issue came to the attention of DG SANTE that would warrant a financial or reputational reservation in DG SANTE's Annual Activity Report.

([47]) C(2021)948 of 12 February 2021 – Commission Decision on delegating powers to HaDEA, amended by C(2021) 9343 of 14 December 2021.

In HaDEA's 2025 Annual Activity Report, the Director reported reasonable assurance on the delegated budget managed by the agency on behalf of DG SANTE and made no reservation with regard to its implementation of the programmes EU4Health and SMP.

Table 7.14 Indicators of control effectiveness as regards legality and regularity

Executive agency HaDEA	*Targets*	2025	2024
Steering Committee meetings with adequate quorum for voting (info: HaDEA has 6 parent DGs)	*4*	**4**	4
Number of "exception reports" relative to the MoUs on the co-operation between DG SANTE and the agency	*n/a*	**0**	0
Budget execution rates of the operational budget transferred to the agency: commitments payments	*99%* *100%*	**99%** **100%**	99.9% 100%
Director's report on control results and error rates endorsed by Steering Committee or Management Board prior to finalisation of DG SANTE's AAR	*Yes*	**Yes**	Yes
Court of Auditors' assurance on the agency's accounts and implementation of the administrative budget of year N-1 without qualification	*Yes*	**Yes**	Yes
Discharge granted for year N-1 and discharge recommendations implemented for year N-2	*Yes*	**Yes**	Yes
Ratio of recovery of the positive budgetary outturn of year N to subsidy paid in year N-1	*n/a*	**1.2**	1.5%

Ad *: HaDEA was set up in February 2021.

EU decentralised agencies

In 2024, DG SANTE was responsible for the following (parts of) EU agencies:

- ❑ European Centre for Disease Prevention and Control (ECDC)
- ❑ European Food Safety Authority (EFSA)
- ❑ European Medicines Agency (EMA)
- ❑ Community Plant Variety Office (CPVO)
- ❑ European Chemicals Agency for its biocides activities (ECHA-biocides)

While CPVO is fully fee-financed, DG SANTE pays annual subsidies from the EU budget to four agencies, including the Chemicals Agency (ECHA) for its biocides activities (the lead responsible DG for ECHA is DG GROW). For detailed information on the agencies, see Annex 13.

The control process is divided into five distinct stages, each with specific control objectives (for more detail see Annex 6).

Stage 1: Ensuring the founding Regulation of the agency is free of legal issues

This control applies whenever an agencies' founding Regulation is amended. In response to COVID-19 pandemic, the role of the agencies has been strengthened as part of the Health Union Package, namely the mandates of ECDC ([48]) and EMA ([49]).

The latest amendment to EFSA's founding Regulation ([50]) dates back to June 2019. From July 2022, EFSA's Management Board includes a member from each Member State, in line with the Common Approach on decentralised agencies.

Stage 2: Assessing the agency's control framework and financial rules

In December 2018, the Commission adopted a revised Framework Financial Regulation (FFR) ([51]) for decentralised agencies. All DG SANTE partner agencies aligned their financial rules to the new FFR by the end of 2019. Through the Commission representative on the agencies' Management Boards and the Commission annual Opinions on the agencies' Single Programming Documents, DG SANTE also monitors the alignment of the agencies' Internal Control Frameworks (ICF) with the Commission's Internal Control Framework. In addition, the Agencies developed their anti-fraud strategies, adopted by the respective Management Boards, and updated them regularly. On request, DG SANTE provides feedback and support on the Internal Control strategy and the relevant control principles.

Stage 3: DG SANTE's monitoring and supervision ("control with the agency")

DG SANTE is a member of the agencies' Management Boards and participates in the meetings throughout the year (2 to 4 meetings depending on the agency). The role of the Management Boards includes the approval of the agencies' annual budgets as well as the adoption of both the multiannual and annual work programmes and the annual activity reports. They are regularly informed on the achievements of the agencies' objectives as well as on all other important issues relating to operational and financial management, internal control, evaluations and audits.

Bilateral meetings between DG SANTE and its partner agencies take place both at senior management and technical level. Five operational Units in DG SANTE are the primary interlocutors for the agencies. A horizontal Unit in Directorate R "Policy and administrative support " ensures a central coordination to promote a coherent approach towards all agencies and to exchange good practices.

([48]) Regulation (EU)2022/2370 of 23 November 2022.
([49]) The Regulation is expected to be adopted by the co-legislators in early 2023.
([50]) Regulation (EU) 2019/1381 of the European Parliament and of the Council on the transparency and sustainability of the EU risk assessment in the food chain amending Regulation (EC) No 178/2002.
([51]) Commission Delegated Regulation (EU) 2019/715 on the framework financial regulation for the bodies set up under the TFEU and Euratom Treaty and referred to in Article 70 of Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council.

Stage 4: Audit and evaluation, discharge

While the Director-General of DG SANTE is accountable for the legality and regularity of the payments of the subsidies to the agencies, the accountability for the regularity and legality of this expenditure resides ultimately with the agencies themselves.

Agencies are subject to periodical external evaluations ([52])

- **ECDC**: the latest evaluation (fourth) was initiated in Q4 2025 (for the period 2017-2025, when applicable). Previous evaluation was finalised in 2019: third external evaluation of ECDC for the years 2013-2017. ECDC has implemented all accepted recommendations as approved by ECDC's Management Board.
- **EFSA**: the third external evaluation was delivered in 2018; the fourth evaluation started in 2024 with a target date of March 2026. A new evaluation (fifth) is planned for Q3 2026 (postponed from Q1). The external study supporting the Commission's Evaluation of EFSA'S Performance 2017-2024 was concluded in December 2025.
- **EMA**: the latest evaluation of the Agency's operation was published on 31 August 2021 and is available in the form of a Report from the Commission to the European Parliament and the Council on the experience acquired with the procedures for authorising and supervising medicinal products for human use, in accordance with the requirements set out in the EU legislation on medicinal products for human use ([53]). The study includes among other aspects, an assessment of the effectiveness and efficiency of the overall structure of EMA's committees, working parties, scientific advisory and expert groups. Currently, a study assessing the extension of EMA mandate is being launched, but no plans for a full evaluation, which will likely depend on the outcome of the pharma review. The current Regulation establishes a 10-year evaluation requirement.
- **CPVO**: the CPVO organises regularly (at least every six years) evaluation of its activities. The most recent exercise in 2022 took the form of a socio-economic impact study on the benefits of the system of Community Plant Variety Rights in the EU. A new evaluation is planned for Q4 2026 (a study to support the evaluation was already initiated in 2025).

European Court of Auditors

Each year, the Court examines the accounts of all agencies, as well as the received revenue and the payments made by the agencies. In October 2025, the Court published its "Annual report on EU agencies for the financial year 2024". The Court gave a positive declaration of assurance to all five agencies to which DG SANTE is parent or associated.

With regard to EMA, the Court raised the following "emphasis of matter" without qualifying its positive opinion: the Court draws attention to the notes to EMA´s accounts, which provide significant disclosures in connection with property-related obligations. The lease on the

([52]) According to their Founding Regulations, external evaluations are to be commissioned for ECDC every five years, for EFSA every six years (every five according to the amendment to EFSA's founding act adopted in 2019), for EMA every 10 years.

([53]) COM(2021) 497 of 31 August 2021.

EMA´s former premises in London runs until 2039 and does not contain a break clause, but the premises can be sublet. In July 2019, the EMA reached an agreement with its landlord, and sublet its former premises to a subtenant until the EMA´s lease expires in June 2039. Since EMA remains a party to the head lease, it could be held liable for the entire amount under the head lease contractual obligation (EUR 375 million) and any other financial obligations possibly arising as result of the premises being vacant. The Court also pointed to the financial situation of the subtenant's ultimate parent company and in particular the filing for bankruptcy of its US and Canada branches. Subsequently, EMA renegotiated its lease with the subtenant in March 2024, including rent reduction and the possibility of early sublease termination. In this respect, EMA made a provision for onerous contract, with a carrying amount of EUR 122.1 million on 31 December 2024 and received a cash reimbursement from the Commission of EUR 11.2 million which has been recognised as income. When EMA issued its accounts, the subtenant had met its contractual obligations, with rental and service charge.

Budgetary Discharge

In May 2025, taking into account the Court of Auditors reports on the agencies' annual accounts, the European Parliament granted the five agencies which receive a subsidy from the EU budget discharge in respect of the 2023 budget implementation. By June 2024, the Court submitted its preliminary findings on the 2024 accounts and underlying transactions of the agencies and gave a positive declaration of assurance to all agencies for which DG SANTE is parent/partner.

DG SANTE, within the limits of its role on the EU agencies' Management Boards and Audit Committees, if applicable ([54]), follows up closely the improvements to be made by the agencies in follow-up to audits, evaluations and discharge recommendations.

Stage 5: DG SANTE's payments of the subsidy

The control issues that came to the attention of DG SANTE did not affect the legality and regularity of DG SANTE's payments of subsidies to the agencies (Table 7.12 below summarises the indicators of control effectiveness as regards legality and regularity).

Further to the Court of Auditors assurance received, DG SANTE cleared all pre-financing payments made to the agencies in 2024 and made the final payments of the subsidies. Thus, no reservation to DG SANTE's declaration of assurance is warranted.

([54]) DG SANTE has two nominated members in ECDC's and one member in EFSA's Audit Committee; EMA and CPVO do not have an Audit Committee and all audit related issues are brought directly to the Management Board and the Administrative Council respectively.

Table 7.15 Indicators of control effectiveness as regards legality and regularity

EU decentralised agencies	*Targets*	2025	2024
Court of Auditors' assurance on EFSA's, EMA's, ECDC's, CPVO's and (since 2015) ECHA's accounts and implementation of their administrative budget of year N-1 without qualification	*Yes* *5 out of 5*	**Yes** **5 out of 5**	Yes 5 out of 5
Discharge granted for year N-1 and discharge recommendations implemented for year N-2	*Yes*	**Yes**	Yes
Ratio of recovery of the positive budgetary outturn of year N to subsidy paid in year N-1	*n/a*	**2.1**	3.9%

7.1.2 Fraud risk management

The controls to prevent and detect fraud are basically the same as those intended to ensure the legality and regularity of the transactions. DG SANTE has developed and implemented its own anti-fraud strategy since 2014, based on the methodology provided by OLAF ([55]). The strategy is updated regularly. The most recent version, covering the years 2021 to 2024, was adopted by the Management Board on 8 November 2021, following the consultation of the Directors' Steering Committee and a peer review coordinated by OLAF. The strategy (2021-2024) took into consideration the new challenges experienced during the COVID-19 crisis and the results of the comprehensive fraud risk assessment exercise, conducted in May-June 2021 with relevant units in DG SANTE. The associated action plan aims to enhance fraud prevention, detection and response capacity in DG SANTE. Its implementation is monitored and the results are reported to DG SANTE management twice a year, at mid-term and at year-end. The strategy and its action plan is currently undergoing an update which is expected to be finalised in the first half of 2026.

Especially important to DG SANTE are the following areas covered by existing procedures; they contribute to the Commission anti-fraud strategy:

- Actions linked to handling "conflict of interest" in agencies, scientific committees and expert groups: most actions implemented, in 2025, DG SANTE assessed the need to revamp the meeting of SANTE's inter-agencies task force on independence with participants and contributions from all five EU agencies for which DG SANTE is partner;
- Involvement in updates of the anti-fraud strategies and action plans of the Health and Digital Executive Agency (HaDEA) and the EU decentralised agencies to which DG SANTE is partner;
- Standing operating procedures for the handling of allegations of fraud, other irregularities and OLAF cases on SANTE intranet;

([55]) Last update of June 2021: Methodology and guidance for services' anti-fraud strategies, Ares(2021)4589215 of 15 July 2021 – and the accompanying action plan; last update of the CAFS' action plan dates 11 July 2023 (COM(2023) 405 final and SWD(2023) 245 final).

- Throughout 2025, active participation in the network "Fraud Prevention and Detection" (FPD) and relevant sub-groups (including on EPPO) chaired by OLAF;
- Raising awareness on fraud prevention and detection in DG SANTE.

In 2025, DG SANTE did not become aware of an allegation of fraud related to DG SANTE's financial transactions.

Objective: The risk of fraud is minimised through the application of effective anti-fraud measures and the implementation of the Commission anti-fraud strategy ([56]) aimed at the prevention, detection and correction ([57]) of fraud		
Indicator 1: Implementation of the actions included in [the department's] anti-fraud strategy over the whole lifetime of the strategic plan (2025-2029) **Source of data:** [the department's] annual activity report, [the department's] anti-fraud strategy, OLAF reporting		
Baseline (2024)	**Target** (2029)	**Latest known results** (situation on 31/12/2025)
80% ([58])	100% ([52]) of due actions implemented each year	83% ([52])

Main outputs in 2025:			
Description	**Indicator**	**Target**	**Latest known results** (situation on 31/12/2025)
Launch the update of DG SANTE's anti-fraud strategy in 2025.	Launch the update of DG SANTE's anti-fraud strategy and preparation of action plan for 2026-2028 to reflect the updated Commission's Anti-fraud Strategy of 2023.	By the end of 2025.	Yes - Launched in July 2025.

([56]) Communication from the Commission 'Commission Anti-Fraud Strategy: enhanced action to protect the EU budget', COM(2019) 176 of 29 April 2019 – 'the CAFS Communication'; Communication from the Commission "Commission Anti-Fraud Strategy Action plan – revision 2023" COM(2023) 405 of 11 July 2023 – "the Communication on the 2023 revision" – and the accompanying revised action plan, SWD(2023) 245– "the revised Action Plan".

([57]) Correction of fraud is an umbrella term, which refers in particular to the recovery of amounts unduly spent and to administrative sanctions.

([58]) 'Baseline' value refers to the percentage of actions under SANTE's anti-fraud strategy 2021-2024; 'Target' value refers to actions under SANTE's anti-fraud strategy 2026-2028; 'Latest known result' value refers to actions under SANTE's anti-fraud strategy 2021-2024.

Description	Indicator	Target	Latest known results (situation on 31/12/2025)
Participation in the network "Fraud Prevention and Detection" (FPD) chaired by OLAF and dissemination of the relevant information stemming from these networks.	Participation in the FPDnet meetings and feed-back given to the financial cell.	At least 4 FPDnet meetings per year and sub-group meetings.	100% In 2025, OLAF organised only 2 plenary meetings and 1 for the sub-group 'Direct Management'. All were attended by SANTE and relevant information was disseminated internally.
Updating fraud indicators and "red flags" for procurement and grants procedures.	Updated lists communicated to relevant staff.	By the end of 2025.	Yes – lists prepared for both procurement and grant procedures.
Actions linked to handling "conflict of interest" in agencies, scientific committees and expert groups.	SANTE permanent group including relevant policy units to discuss common issues to the agencies for which SANTE is partner and assess the need for a meeting of the SANTE inter-agencies Task Force on independence.	1 meeting per year of the SANTE permanent group to evaluate the need for a meeting on the SANTE task force (TF) on independence, with all-agencies for which SANTE is partner.	Yes – 1 meeting took place in March 2025.

A. Compulsory for all departments:

1. Reports and documentation considered for the assessment of the DG's functioning in view of the AOD's assurance:

7.2 Reports and documentation considered for the assessment of DG SANTE's functioning in view of the AOD's assurance

Assurance is provided on the basis of information on the efficiency and effectiveness of internal control systems and governance processes. The management monitors the functioning of the internal control systems on a continuous basis and carries out an objective examination with internal and external auditors. The results are explicitly documented and reported to the Director-General. The following reports / documentation have been considered:

- Annual reports on budget implementation drafted by the Authorising Officers by Sub-delegation, including their hand-over reports;

- Reports of the central financial cell on the recorded exceptions/non-compliance events or “confirmation of instructions” according to Article 92(3) of the Financial Regulation;
- Report of the Public Procurement Committee ("Comité des Marchés Publics") on ex-ante controls of public procurement procedures;
- Audit reports and the annual overview report of DG SANTE’s on-the spot controls;
- Report of the Director in charge of Risk Management and Internal Control (RMIC) on the annual assessment of the internal control principles;
    - Limited conclusion of the Internal Auditor on the state of internal control, and the observations and recommendations reported by the Internal Audit Service (IAS);
    - The observations and the recommendations reported by the European Court of Auditors (ECA);
- Reports on control results from the Health and Digital Executive Agency (HaDEA);
- Reports on control results from EU decentralised agencies to which DG SANTE is partner.

7.3 Financial Regulation: Additional reporting requirements resulting from the 2018 and 2024 revisions

In line with the requirements of the Financial Regulation, DG SANTE reports for the year 2025:

1. No cases of any in-kind donation made to the Union, for the purposes of humanitarian aid, emergency support, civil protection or crisis management aid (FR art 25.3).
2. No cases of "confirmation of instructions" (FR art 92.3).
3. No cases of financing not linked to costs (FR art 125.3).
4. No Financial Framework Partnerships >4 years (FR art 131.4).
5. No cases of flat-rates >7% for funding indirect costs (FR art 184.6).
6. 1 derogation from the principle of non-retroactivity pursuant to Article 196 of the Financial Regulation.
7. No cases of financial support to third parties >EUR 60 000 (FR art 207).
8. No cases of non-financial donations provided in the form of services, supplies or works (FR art 244.3).

DG SANTE has one case to report of “derogations from the principle of non-retroactivity” pursuant to FR article 196, since all grants related to veterinary and plant emergency measures derogate from FR article 196.2 as set out in the Single Market Programme Regulation ([59]), article 13(1a).

([59]) Regulation (EU) 2021/690 of 28 April 2021 on the Single Market Programme (SMP).

7.4 Economy of controls

The main economy indicators monitored in 2024 focussed on the resources employed for internal control activities. They encompass DG SANTE's staff carrying out the monitoring tasks through the different stages of the control processes as defined in Annex 6. The costs are calculated on an all-cost basis without including an overhead rate. They are based - where possible – on estimates made in DG SANTE's Unit Management Plans approved by the Director-General.

Table 7.17 Overview of DG SANTE's estimated cost of controls at Commission level (the absolute values are presented in EUR ([60]))

- Overview of SANTE's estimated cost of controls at Commission (EC) level

EXPENDITURE — The absolute values are presented in EUR

SANTE	Ex ante controls***			Ex post controls			Total	
	(a)	(b)	(c)	(d)	(e)	(f)	(g)	(h)
Segment of expenditure (as in Table X) / Relevant Control System (RCS) / Other as defined in Annex 6 of the AAR*	EC total costs	related payments Made	Ratio (%)** *(a)/(b)*	EC total costs	total value verified and/or audited	Ratio (%) *(d)/(e)*	EC total estimated cost of controls *(a)+(d)*	Ratio (%)** *(g)/(b)*
Grants to Member States in the Food Safety policy area	1,865,130.00 €	130,792,384.58 €	1.43%	- €	- €	0.00%	1,865,130.00 €	1.43%
Public procurement	4,756,106.04 €	71,589,806.13 €	6.64%	- €	- €	0.00%	4,756,106.04 €	6.64%
Contribution agreements	1,276,523.00 €	31,644,486.84 €	4.03%	- €	- €	0.00%	1,276,523.00 €	4.03%
Subsidies to agencies	1,973,112.00 €	362,143,723.90 €	0.54%	- €	- €	0.00%	1,973,112.00 €	0.54%
OVERALL total estimated cost of control at EC level for expenditure	**9,870,871.04 €**	**596,170,401.45 €**	**1.66%**	- €	- €	**0.00%**	**9,870,871.04 €**	**1.66%**

NON-EXPENDITURE ITEMS ****

SANTE	Ex ante controls***			Ex post controls			Total	
	(a)	(b)	(c)	(d)	(e)	(f)	(g)	(h)
Segment of expenditure (as in Table X) / Relevant Control System (RCS) / Other as defined in Annex 6 of the AAR*	EC total costs	related amounts	Ratio (%)** *(a)/(b)*	EC total costs	total value verified and/or audited	Ratio (%) *(d)/(e)*	EC total estimated cost of controls *(a)+(d)*	Ratio (%)** *(g)/(b)*
Only applicable for DGs with non-expenditure items								
Intangible Assets - internally generated IT software	0.00 €	- €	N/A	- €	- €	N/A	0.00 €	N/A
Inventories of antigen stocks for animal diseases	0.00 €	- €	N/A	- €	- €	N/A	0.00 €	N/A

** if the control costs are not attributable to a single RCS and may relate to a 'mix' of expenditure, revenue, assets/liabilities, etc, they may be grouped*

*** ratio possibly "Not Applicable (N/A)", e.g. if a RCS specifically covers an Internal Control Objective such as safeguarding sensitive information, reliable accounting/reporting, etc*
**** any 'holistic' control elements (e.g. with 'combined' ex-ante & ex-post characteristics) can be reported in the ex-ante column provided that a footnote clarifies this (their nature + their cost). Example: MS system audits in shared management.*
***** These include revenue operations (e.g. assigned revenue, fines, interest); assets (e.g. (in)tangible or financial assets, inventories, treasury) and financial liabilities or 'off balance sheet' items (e.g. employee benefits, guarantees offered or other commitments)*

Details of the estimated cost of the control activities related to payments for salaries and/or missions executed by DG HR/PMO are reported in their respective annual activity report(s).

Details about the estimated cost of the control activities related to procurement and provided by REA are reported in the Annual activity report of REA.

([60]) The cost of controls for intangible assets and inventories is included in DG SANTE's overall total estimated cost of controls as it cannot be provided separately.

ANNEX 8: Reporting on the internal and external audits and assessing the effectiveness of internal control systems

8.1 Audit observations and recommendations

This part includes audits of the European Court of Auditors (Court) and the Commission's Internal Audit Service (IAS) as well as DG SANTE's audit follow-up.

8.1.1 Internal Audit Service of the Commission (IAS)

During 2025, the IAS launched three new audits: two audits in DG SANTE covering 'Data management in DG SANTE' and ''Effectiveness of DG SANTE's processes to avoid conflict of interest'', as well as a multi-DG audit on 'Management of requests for access to documents', in which DG SANTE is a sampled DG. As of December 2025, the audits were at a very early stage and the reports are expected to be issued in 2026. No new recommendations issued by the IAS in 2025 concerning DG SANTE.

During 2025, DG SANTE worked on implementing all open recommendations from past IAS audits and closed 3 "important" recommendations: (i) 'Address weaknesses in i.RASFF' from the audit on 'European Commission actions against food fraud in DG SANTE, DG AGRI and OLAF', (ii) 'IT security plan for MDR EUDAMED' and (iii) 'Completeness and accuracy of IT security information' from two IAS audits on 'IT security risk management'.

As of December 2025, DG SANTE has one IAS open recommendation rated "very important", which pertains to the performance audit on the 'European Commission actions against food fraud in DGs SANTE, AGRI and OLAF'. DG SANTE's target date for implementation of the action plan is December 2026. DG SANTE has already started work on the implementation of this recommendation. A structured process has been put in place to ensure the manual exchange of relevant information between the OFIS and RASFF networks and to address situations of potential public health risk from OFIS notifications. Furthermore, DG SANTE is currently designing a new generation of iRASFF and reassessing in detail the feasibility and requirements for achieving effective IT interoperability with OFIS.

DG SANTE had implemented the other two "very important" audit recommendations from the audit on 'European Commission actions against food fraud in DGs SANTE, AGRI and OLAF' according to plan, notably through drafting and updating Standing Operating Procedures, improving IT reporting tools and providing training to Member States and other participating countries. The IAS reviewed these actions and accepted their implementation.

8.1.2 European Court of Auditors (ECA)

A. ECA's financial audits: 2024 DAS

Every year the European Court of Auditors (ECA) audits revenue and expenditure of the EU budget and provides its opinion on the extent to which the annual accounts are reliable, and income and spending comply with the rules and regulations. The ECA published its 2024 Annual Report (2024 DAS) on the implementation of the EU budget for the 2024 financial year on 10 October 2025.

The structure of the ECA's 2024 report is adapted to the budget headings of the Multi-annual Financial Framework (MFF) 2021-2027. DG SANTE is part of the policy chapter 6 "Cohesion, resilience and values". In its report, the ECA raised one finding related to the procurement procedure and signature of an Advance Purchase Agreement for COVID-19 vaccines, but did not report an error rate for that transaction. No recommendations were issued for DG SANTE. DG SANTE does not have open financial recommendations.

B. ECA's special reports on performance audits in DG SANTE

In 2025, the European Court of Auditors published one Special Report related to performance audits in DG SANTE. The Commission (partially) accepted all recommendations and DG SANTE launched the preparations of the action plans to implement them. There were three additional ongoing audits by the ECA in DG SANTE for which the Special Reports were not yet issued as of December 2025. They cover the topics of Europe's Beating Cancer Plan, Olive Oil control systems and European Union's approach to forever chemicals. For the latter two, DG SANTE is associated DG.

Critical shortages of medicines *(Special Report 19/2025, published on 17 September 2025)*

There are three recommendations in total, jointly addressed to both Commission services and EMA. The objective of the audit was to assess whether EU measures to ensure medicine availability were effective. The ECA concluded that EU measures were of added value, but structural problems remain and fragmentation within the single market continues to hinder the availability of medicines across the EU.

The recommendations addressed to DG SANTE were to:

- Ensure timely reporting of shortages of centrally authorised medicines to EMA and appropriate measures to resume continuous supply of medicines in the event of a critical shortage;
- Launch comprehensive coordinated action to address root causes of medicine shortages;
- Improve the functioning of the single market for medicines by addressing barriers, i.e. better application of the Transparency Directive by Member States, enhancing consistency of medicine packages within the EU and assessing the impact of supply quotas and parallel trade on shortages.

DG SANTE is responsible for the implementation of six sub-recommendations of which four are partially accepted. This is because the full implementation depends on the outcome of the ongoing co-legislation process and the Commission is not in a position to make specific commitments in relation to possible legislative proposals. As a result, the partially accepted recommendations and risks related to them do not have any significant impact on the assurance

provided by the Director-General of DG SANTE and, therefore, the declaration of assurance is not qualified.

DG SANTE is preparing an action plan to address the implementation of all sub-recommendations addressed to it.

8.1.3 DG SANTE's follow-up on the ECA's audits

DG SANTE addresses all audit recommendations by proportionate action plans and monitors their implementation regularly. The Director in charge of Risk Management and Internal Control (RMIC) reports on the progress made twice a year, firstly, in the context of the mid-term report on internal control, and secondly, during the annual activity reporting. All open recommendations of DG SANTE relate to performance elements.

The follow-up of the ECA's recommendations as well as recommendations made by the discharge authorities in previous years is organised by DG BUDG through the RAD-database (Recommendations, Audit and Discharge). DG SANTE launches systematic updates twice a year (July/August and December/January).

In 2025, DG SANTE fully implemented the outstanding recommendations resulting from the audits on 'EU Health Digitalisation' (1 recommendation) and 'Protection of wild pollinators in the EU' (2 recommendations).

There are no outstanding "very important" recommendations stemming from ECA audits. DG SANTE monitored the implementation of all other outstanding recommendation pertaining to four additional performance audits and put in place relevant actions to progress with their achievement in accordance with the established action plans. The outstanding recommendations are:

(1) EU's response to the COVID-19 pandemic (*Special Report 2024/12 published on 4 September 2024*):

(i) Ensure that clear coordination mechanisms are in place to help the EU respond quickly to future health emergencies.
The implementation of the recommendations is ongoing according to the agreed action plan.

(2) Food labelling in the EU (*Special Report 2024/23 published on 25 November 2024*):

(i) Address the gaps in the EU legal framework for food labelling;
(ii) Step up efforts to analyse labelling practices;
(iii) Monitor consumer expectations and take action to improve their understanding of food labelling;
(iv) Strengthen Member States' checks on voluntary labels and online retail;
(v) Improve reporting on food labelling.
The implementation of the recommendations is ongoing according to the agreed action plan.

(3) Tools facilitating travel within the EU during the COVID-19 pandemic (*Special Report 2023/01 published on 11 January 2023*)

(i) Addressing the reasons for the low uptake of EU digital passenger locator forms;
(ii) Making the EU tools, which were used to facilitate cross border contact tracing during crises, easier for EU citizens to access.

The two recommendations are partially implemented, and DG SANTE aims to implement the recommendations by the end of 2026.

(4) *Animal welfare in the EU: closing the gap between ambitious goals and practical implementation* (*Special Report 2018/31 published in November 2018*):

(i) Reflect on how to address the conclusions of the evaluation and publish the results of its assessment;
(ii) Define baseline and target indicators to measure Member States' degree of compliance.

The full implementation of the two recommendations on "Animal Welfare" is delayed as key steps in DG SANTE's developing Commission proposals were outside DG SANTE's control. DG SANTE aims to implement the recommendations by the end of 2026.

8.2 Assessment of the effectiveness of internal control systems

8.2.1 Changes in DG SANTE's control environment

In 2025, no major changes to DG SANTE's control environment took place, except that in January 2025, DG SANTE, similarly to all Commission services, transitioned to a new IT accounting system, SUMMA. Issues encountered during the first months of deployment have been communicated to DG BUDG and were resolved with the support of the central services. Staff members took part in important trainings to keep up the good performance and to maximise the benefits of further modernisation, harmonisation and standardisation of DG SANTE's financial business processes.

In June 2025, DG SANTE undertook a small re-organisation to better adjust its limited human resources. This did not have significant effect on the control environment.

8.2.2 Annual assessment of internal control by management

In its internal control system, DG SANTE embedded continuous monitoring measures to ensure that its management and internal control framework is effective. DG SANTE has also considered the risks and focuses its control resources on those areas where risks are the highest, while ensuring adequate control coverage over all activities. DG SANTE followed the methodology proposed in the "implementation guide of the internal control framework of the Commission".

8.2.2.1 Annual assessment methodology

The annual assessment on the implementation of the Internal Control Principles (ICP) was finalised in the first quarter of 2026 and was endorsed by the Management Board in its meeting on 23 March 2026. The following four elements underpin the annual assessment since several years:

(a) Internal control monitoring criteria: evaluation of the indicators as defined in the Management Plan; several indicators are based on the results of staff survey organised by DG HR to get a better insight into the effectiveness of selected control principles. The latest general staff survey of DG HR was carried out in November 2025 and the results from DG SANTE's report on the HR survey were used to assess the indicators.

(b) Exceptions to rules and procedures, including non-compliance events or cases of "confirmation of instructions" as well as issues raised in management reports received from the authorising officers by sub-delegation: scrutiny of the reports that could point to control deficiencies;

(c) Audit observations of the IAS and the European Court of Auditors as well as findings from DG BUDG's validation of local systems (if available): analysis of the results of the audits and audit follow-up work to assess the impact on the internal control system;

(d) Results of the internal desk review including contributions of key staff supporting important elements of the set up and functioning of internal controls and the follow-up of management action plans stemming from management's risk assessment.

8.2.2.2 Results of the annual assessment

(a) Internal control monitoring criteria

DG SANTE embedded continuous monitoring measures in its internal control system to ensure its effectiveness. The assessment on the basis of the defined internal control monitoring criteria led to a positive conclusion on the effectiveness of the internal control system, meaning that the components and principles are present and functioning, but some improvements are needed for minor deficiencies. These relate to the following Internal Control Principles: ICP 1 on ethical values and integrity; ICP 4 on staff allocation and professional development, functions which are only partially under DG SANTE management; ICP 9 on "change management".

- ICP 1 and 4: In 2025, the main issues remain. HR services including ethics correspondent and mobility are centralised in DG HR. A higher visibility to SANTE staff on the role and work of the ethics correspondent in DG HR is needed. As regard the staff allocation, the results of the most recent HR staff survey (of October 2025) – in comparison to the 2023 results – point to a slight improvement of the internal control principle. Where possible, DG SANTE should continue actions aimed at further consolidating the positive trend. Strengthening ICP principles 1 and 4, DG SANTE's HRC team systematically met all newcomers individually throughout the year and ensured, together with their managers, smooth integration into the DG. Special sessions were also organised for all Blue Book and NEPT trainees to get acquainted with the work of DG SANTE.
- ICP 9: The principle to identify and assess changes, which could significantly impact the internal control system, is present and functioning overall: DG SANTE assesses risks that could arise from changes in the environment and their implications on the internal control system. However, staff perception of change embracement in DG SANTE shows room for improvement (as per the HR staff survey of 2025).

DG SANTE's internal control strategy was updated comprehensively in December 2024 and endorsed by the Management Board in January 2025. This important update took into account the new Multi-annual Financial Framework (2021-2027), the externalisation of budget implementation tasks to

HaDEA, the organisational changes in DG SANTE in October 2022, the new Financial Regulation of 2024 and the transition from ABAC to SUMMA.

(b) Exceptions to rules and procedure

Throughout the year, the functioning of the internal control system was closely monitored by the systematic registration of so-called "exceptions", non-compliance events and internal control weaknesses to ensure transparency and accountability despite derogations from rules and procedures. In 2025, the most important exceptions were the following:

- In two cases, the end date of a specific contract falls after the maximum end date for implementation of specific contracts under the relevant Framework Contract. No financial or reputational impact;
- In two cases, there was a deviation from article 111 of the Financial Regulation as transport costs were incurred and licenses renewal/ use started before a budgetary commitment was made;
- Non-compliance with the Financial Regulation when credits for certain necessary actions had to be committed to guarantee continuity of work and compliance with legal obligations, although the financing decision for the EU4Health 2025 work programme was delayed due to the transition to the new College and the need to reflect the new political priorities.
- Non-compliance with the principle of annuality and in particular with article 12.1 of the FR concerning payment of Contribution Agreement, as SUMMA doesn't allow the use of regularization payment between different purchase orders.
- In one case, an exception to DG SANTE's procedures was prompted by a prior non-compliance with the Financial Regulation due to procedural issues;
- In one case, an expert was engaged under a low value contract, although the contract conclusion was delayed due to technical (IT) difficulties in the system for experts;
- In one case, the signing of amendment to extend the end date of a contract has been done outside of the system, due to the system being down as a result of the SUMMA migration.
- In one case, there was a deviation from DG SANTE's procedure on expenditure operations related to late receipt and payment of an invoice for an event from 2023.

In each case, the underlying causes behind the exceptions and weaknesses were analysed and drawn to the attention of the Director-General. Management assessed that, overall, the existing controls are sufficient and that the procedures in place function well.

(c) Audit observations

- The feedback received from the European Court of Auditors and the IAS did not reveal any significant internal control issues and no financial recommendations. No OLAF investigation or IDOC report was addressed to DG SANTE.

- In 2025, DG SANTE closed one open “important” recommendation and implemented some actions towards the implementation of the last open audit recommendation (rated "very important") of the IAS audit on ‘European Commission actions against food fraud in DGs SANTE, AGRI and OLAF’ in accordance with DG SANTE’s action plan and in close co-operation with DG AGRI. DG SANTE believes that the mitigating measures it has put in place do not put the effectiveness of DG SANTE’s internal control system into question (see part 8.1.2 above for more detail on the audits and DG SANTE’s actions).
- In 2025 DG SANTE implemented one “important” recommendation from the IAS audit on ‘IT security risk management in the Commission’ in accordance with the accepted action plan and worked towards the implementation of the remaining three “important” recommendations which are not yet due.
- The last outstanding recommendation ‘IT security plan for MDR EUDAMED’ from the audit on ‘IT security management’ was implemented in 2025.
- The ECA audit on ‘Critical shortages of medicines’ addressed 3 joint recommendations to DG SANTE, EMA and other associated Commission services. DG SANTE is preparing an action plan for the implementation of all recommendations addressed to it (see part 8.1.2 above for more detail on this audit).
- DG SANTE’s centralised function to follow up on audit recommendations ensures a timely management of and reporting on the implementation of audit recommendations. All open recommendations from IAS and ECA audits were systematically monitored and reported on twice in 2025 through the RAD-database (Recommendations, Audit and Discharge).
- DG SANTE does not have any open “very important” recommendations stemming from ECA audits. The full implementation of the two recommendations on “Animal Welfare” is delayed as key steps in DG SANTE’s developing Commission proposals were outside DG SANTE’s control. DG SANTE considers that this does not have a material impact on the assurance.

(d) Results of the internal desk review

- The financial verifying agents, the central function for managing procurement procedures and the Public Procurement Committee (PPC) assisted the authorising officers by sub-delegation in the review and validation of transactions and procedures. Their ex-ante controls and checks, embedded in the procedures, did not reveal any significant internal control weaknesses.
- With regard to budget implementation in 2025, all authorising officers by sub-delegation prepared their annual reports for the Director-General. The Directors in charge of EU decentralised agencies also prepared a report on any policy, financial and/or control issue or risk that came to attention and could have an impact on the Director-General’s declaration. DG SANTE assessed that the issues highlighted do not impact negatively on the Director-General's declaration of assurance.

8.2.2.3 Risk management and reputational events

The risk identification and assessment process is an essential management activity and an important part of the DG SANTE’s internal control process. It facilitates the establishment of specific internal control strategies focussing on the activities and domains representing the highest risks. To be effective, risk management is fully integrated into DG SANTE's planning and control cycle. Since 2010, this is achieved by including the identification of risks and mitigating actions into the annual Management Plan (MP).

The risk assessment exercise for the MP starts each year in September and is finalised in November. Further to the input received from all Units, the results of the risk assessment are discussed in the Directors' Steering Committee and the Management Board to identify DG SANTE's critical risks to be reported in the Management Plan.

With a view to monitoring the implementation of the action plans, each year in August/September DG SANTE prepares a progress report and communicates it to the Commissioner in the context of the mid-term report. In 2025, the monitoring of the implementation of the action plan addressing DG SANTE's critical risks was carried out in August/ September, in parallel with the risk identification exercise for the year 2026. Actions to address the Unit risks, which are not included in SANTE's critical risks, are organised at the level of the Units.

In 2025, no major event impacting the Director-General's declaration of assurance occurred.

ANNEX 9: Specific annexes related to "Control results" and "Assurance: Reservations"

Table 9 Estimated risk at payment and closure

Table X : Estimated risk at payment and at closure (amounts in EUR mios) - for parent DGs

DG SANTE	Payments made (2025;MEUR)	minus new prefinancing (plus retentions made) (in 2025;MEUR)	plus cleared prefinancing (minus retentions released and deductions of expenditure made	Relevant expenditure (for 2025;MEUR)	Detected error rate or equivalent estimates	Estimated risk at payment (2025;MEUR)	Adjusted Average Recoveries and Corrections (*adjusted* ARC; %)	Estimated future corrections (and deductions) (for 2025;MEUR)	Estimated risk at Closure (2025;MEUR)
-1	-2	-3	-4	-5	-6	-7	-8	-9	-10
RCS 1 - Grants in Food Safety policy area (Emergency Measures)	130.79	- 100.79	146.92	176.93	1.99% - 1.99%	3.52 - 3.52	0.00% - 0.00%	0.00 - 0.00	3.52 - 3.52
RCS 2 - Public procurement and other grants	76.88	- 1.01	0.74	76.61	2.00% - 2.00%	1.53 - 1.53	0.00% - 0.00%	0.00 - 0.00	1.53 - 1.53
RCS 4 - Contribution agreements with international organisations and EU decentralised agencies	31.64	- 30.91	2.52	3.25	2.00% - 2.00%	0.06 - 0.06	0.00% - 0.00%	0.00 - 0.00	0.06 - 0.06
RCS 5 - EU Decentralised agencies - Subsidies	299.91	- 299.91	295.18	295.18	0.00% - 0.00%	0.00 - 0.00	0.00% - 0.00%	0.00 - 0.00	0.00 - 0.00
Total without contribution to EA's operating budget	**539.23**	**- 432.62**	**445.36**	**551.97**		**5.12 - 5.12**	**0.00% 0.00%**	**0.00 - 0.00**	**5.12 - 5.12**
					Overall risk at payment in %	**0.93% - 0.93%** *(7) / (5)*		**Overall risk at closure in %**	**0.93% - 0.93%** *(10) / (5)*
RCS 3 - Health and Digital Executive Agency (HADEA)	62.24	- 62.24	54.76	54.76	0.00% - 0.00%	0.00 - 0.00	0.00% - 0.00%	0.00 - 0.00	0.00 - 0.00
Sub-total contributions (if more than one)	62.24	- 62.24	54.76	54.76		0.00 0.00		0.00 0.00	0.00 0.00
Total DG (with contributions to EAs)	**601.46**	**- 494.86**	**500.13**	**606.73**					

Notes to the table:

- To column (1) Relevant Control Systems differentiated per relevant portfolio segments and at a level which is lower than the total.
- To column (2) Payments made after the preventive (ex-ante) control measures have already been implemented earlier in the cycle. For Cross-SubDelegations (Internal Rules Article 12), the reporting remains with the Delegating departments.
- To column (3) New pre-financing actually paid by DG SANTE during the financial year (i.e. excluding any pre-financing received as a transfer from another department).
- To column (4) Pre-financing actually cleared during the financial year (i.e. their 'delta' in the Financial Year 'actuals', not their 'cut-off' based estimated 'consumption').
- To column (5) For the purpose of equivalence with the European Court of Auditors' (ECA) scope of the EC funds with potential exposure to legality & regularity (see the ECA's Annual Report methodological annex 1.1), our concept of "relevant expenditure" includes the payments made, subtracts the new pre-financing paid out, and adds the pre-financing actually cleared during the Financial Year. This is a separate and 'hybrid' concept, intentionally combining elements from the budgetary accounting and from the general ledger accounting.

- To column (6) In this column, DG SANTE discloses equivalent estimates to the detected error rates as follows (i) a conservative estimate of 2% was used for expenditure based on grants to Member States, for which extensive ex-ante controls are in place, and grants to international organisations, but results on ex-post error rates are not yet available; (ii) a conservative estimate of 2% was used for expenditure based on public procurement for which in general no financial audits are carried out; (iii) for low-risk and zero-risk types of expenditure, where there are indications that the equivalent error rate might be close to 'zero': the subsidies paid by DG SANTE to decentralised agencies as part of their establishment and core tasks are considered error-free types of expenditure and the rate applied is 0%.
- To column (7) The estimated risk at payment is calculated by multiplying he error rate (column 6) with the relevant expenditure (column 5).
- To column (8) The adjusted average recovery and corrections percentage is to a certain extent based on the 7-year historic Average of Recoveries and financial Corrections (ARC), which is the best available indication of the corrective measures each department applied over the past years as a result of ex-post controls. DG SANTE adjusted this historic average from 0.17% to 0.0% considering that the ex-post controls of the past years until 2022 are no longer relevant since the budget implementation of the programmes has been transferred to HaDEA in 2021. The budget that remained with DG SANTE was implemented following ex-ante control systems, including on-the-spot financial audits prior to the final payment. Thus, the future corrections are prudently estimated at 0.0%.

RCS on public procurement covers/includes administrative expenses related to salaries and/or missions previously reported by the PMO and/or DG HR. More information can be found in Annexes 6 and 7.

ANNEX 10: Reporting – Human resources, digital transformation and data management, and sound environmental management

Human Resource management

Objective: DG SANTE employs a skilled, diverse and motivated workforce to deliver on the Commission's priorities		
Indicator 1: Percentage of female middle managers **Source of data:** SYSPER		
Baseline (2024)	**Target (2029)**	**Latest known results (situation on 31/12/2025)**
55%	Maintain at least 50%	**61%**
Indicator 2: Staff engagement index **Source of data:** Commission staff survey [data to be provided by DG HR]		
Baseline (2023)	**Target ([61]) (2029)**	**Latest known results ([62]) (situation on 31/12/2025)**
77%	Maintain	New Staff Engagement index: 80% Old Staff Engagement index: No change

Main outputs in 2025:			
Description	**Indicator**	**Target**	**Latest known results (situation on 31/12/2025)**
Appointment of female Deputy Head of Unit	% of female Deputy head of Unit	>50%	**45%** (3 new female Deputy Head of Unit were recruited on 1/1/2026 increasing the figure to 52%)

([61]) The Commission baseline score for the Staff Engagement Index is 73% (based on the 2023 staff survey results).

([62]) A new method of measuring staff engagement was introduced in 2025. The new Staff Engagement Index provides a more comprehensive view of staff engagement covering purpose, pride and motivation, autonomy and growth and collaboration and trust. The old Staff Engagement Index, which focused more on job content and relations with immediate colleagues and manager, will be used exclusively for comparisons with past data.

Description	Indicator	Target	Latest known results (situation on 31/12/2025)
Training programme for management talent development	Number of female AD Officials with management potential trained	4 (MDP + SANTE own initiative)	**1** (Only 2 female candidates expressed an interest compared to 10 male)
Regular organisation of virtual staff meetings with the Director-General	Number of events	4	**Achieved**
Systematic participation of Senior Management in Unit meetings	Number of unit meetings	Every two meetings and at least 8 times a year	**Directors met at least 5 times with colleagues from their Units, individually or collectively including team buildings and meetings with teams.**
Participatory workshops on key policy and organisational topics (AI, Ethics, DIO action)	Number of workshops	6	**Achieved**
Social responsibility activities for staff	Number of events	4	**Achieved**

Digital transformation and data management

Objective: DG SANTE is using innovative, trusted digital solutions for better policymaking, data management and administrative processes to build a digitally transformed, user-focused and data-driven Commission

Indicator 1: Digital Culture: % of statutory staff that has completed at least one IT training course ([63])

Source of data: Digital Commission Dashboard (data measured at DG-level)

Baseline (2024)	Interim milestone (2027)	Target (2029)	Latest known results (situation on 31/12/2025)
43.19%	20% increase compared to baseline	40% increase compared to baseline	32% Note: The dashboard does not collect any of the internal trainings organised by SANTE, which explains the lower figure.

([63]) This KPI will be accompanied by an informative package that will be shared in AAR templates on a yearly basis. The package will include: (i) link to implementing guidelines – list of training courses available in EU Learn; and (ii) dedicated instructions on how to register a new training course in EU Learn (when this is organised at DG level directly by the DG), in order to record the actual number of participants and sessions.

Indicator 2: Seamless digital environment: cloud adoption – % of IT systems utilising cloud infrastructure services compared to the total number of IT systems **Source of data:** Digital Commission Dashboard (- data measured at DG-level)			
Baseline (2024)	**Interim milestone (2027)**	**Target (2029)**	**Latest known results (situation on 31/12/2025)**
25.53%	150% increase compared to baseline: 64%	200% increase compared to baseline: 77%	32%

Indicator 3: Maturity level in implementing corporate data policies across four key areas: data management, ownership and responsibilities, data quality, and data skills (basic, developing, established, advanced, or trendsetting). **Source of data:** Commission Data Maturity Dashboard			
Baseline (2024)	**Interim milestone (2027)**	**Target (2029)**	**Latest known results (situation on 31/12/2025)**
Established	Established	Advanced	Established

Indicator 4: Compliance indicator ([64]): percentage of staff trained on data protection compliance combined with the percentage of public records of processing operations reviewed within the last two years. **Source of data:** DPMS and internal statistics on trainings and other awareness raising activities			
Baseline (2024)	**Interim milestone (2027)**	**Target (2029)**	**Latest known results (situation on 31/12/2025)**
81.5%	>90%	100%	84.5% (86,1 % of staff attended data protection awareness-raising activities 82,9 % of records updated)

([64]) The compliance indicator is calculated with a 50% weight attributed to the following two values: first, the number of public records with a publication date within the last 2 years / public records of the department. Second, the percentage of staff in the department who have attended data protection awareness-raising activities"

Main outputs in 2025:			
Digital culture			
Output	**Indicator**	**Target**	**Latest known results (situation on 31/12/2025)**
Artificial Intelligence	Number of sessions on use of corporate AI to all SANTE Staff and management Tailored sessions for all SANTE Units	2 sessions 1 session per Unit	**5 sessions held in total:** **1 Seminar for Senior & Middle Management** **3 AI Roadshows** **1 Knowledge Hour** **2 DG wide sessions held on implementing AI in day-to-day work**
Digital-ready EU policymaking			
Output	**Indicator**	**Target**	**Latest known results (situation on 31/12/2025)**
Digital-ready EU policymaking	Percentage of DG SANTE legislative proposals that address the digital aspects in the Legislative, Financial and Digital Statement (LFDS) relative to the total number of DG SANTE legislative proposals within scope of the LFDS.	100% of the proposals address digital aspects	**All 4 proposals with a LFDS address the digital aspects.**
Business driven Digital Transformation			
Output	**Indicator**	**Target**	**Latest known results (situation on 31/12/2025)**
Data findability	Number of IT solutions reviewed to identify datasets and publish updates on the Corporate data catalogue	15/41 IT solutions *(baseline 2024: 3/41 IT solutions)*	**15**

Output	Indicator	Target	Latest known results (situation on 31/12/2025)
Transparency and data reuse	Number of solutions publishing data through the SANTE data platform for: a) Open data b) Downstream systems	a) 24 datasets / 10 solutions b) + 5 datasets / + 2 solutions *(baseline 2024):* *a) 12 datasets / 4 solutions b) 3 datasets / 3 solutions*	**a) 12 datasets / 4 solutions** **b) 15 datasets / 7 solutions** To reduce manual work related to publishing open data, SANTE has paused work whilst investigating tools to help automate this work.
Seamless Digital Environment			
Output	**Indicator**	**Target**	**Latest known results** (situation on 31/12/2025)
IT Legacy ratio	Ratio of fully supported, depreciated and unsupported IT systems (hosted in the corporate datacentre) per department	50%: 50%: 0% (Fully Supported, Deprecated, Unsupported) *(Baseline 2024: 11%, 89%, 0%)*	**17; 81%, 2%** The majority of Cloud migration work will take place in 2026.
Green, resilient and secure digital infrastructure			
Cybersecurity	% of IT Security plans that are updated in the last 2 years	100%	**100%**
Data protection	% of IT solutions reviewed that are in alignment with the EUDPR	100% of IT solutions reviewed	**100%**

Sound environmental management

Objective: Reaching climate neutrality by 2030 and a reduced environmental footprint for the Commission.

Indicator: % reduction in emissions from staff professional travel (t CO2eq).

Source of data: DG/department emissions report from Mips+

Baseline (2019)	Target (2030)	Latest known results (situation on 31/12/2025)
2.11 thousand tonnes([65])	50% of reduction (baseline 2019)	**0.91 thousand tonnes (reduction of 56.8%)**

([65]) As of 2025 emissions from staff professional travel are measured through the Qlik Sense dashboard, hence the baseline has been changed to reflect the new tool.

Main outputs in 2025:			
Description	**Indicator**	**Target**	**Latest known results (situation on 31/12/2025)**
Review of DG's business travel trends /patterns (based on corporate EC-staff's professional trips (missions) with a view to optimise and gradually reduce CO_2 emissions (e.g. by optimising the number of participants in the same mission, promoting more sustainable travelling options, promoting videoconferencing/ virtual events as an alternative)	CO_2 (t) emissions from DG's missions	Maintain the value for emissions from staff professional missions below the 50% reduction target compared to the 2019 baseline.	**Achieved**
Increase in the use (number of) video-conferencing rooms in Grange for meetings with stakeholders (avoiding business trips) in the DG	Increase/decrease compared to 2025	Increase	**Achieved** (increase of 19%)
Participation in the seasonal energy saving action (closing DG's buildings)	% of SANTE's buildings participating in the annual BEST energy saving actions in winter	75% (3 out of 4: 2 in BXL, 1 in LUX, 1 IRL) 75% (3 out of 4: 2 in BXL, 1 in LUX, 1 IRL)	**75%** (3 out of 4: 2 in BXL, 1 IRL) **50%** (2 out of 4: 2 in BXL, IRL not applicable as the premises are not air-conditioned)
	% of SANTE's buildings participating in the annual BEST energy saving actions in summer		

Description	Indicator	Target	Latest known results (situation on 31/12/2025)
Communication and awareness raising actions in line with EMAS corporate campaigns (including corporate Velo Mai campaign, Grange-specific internal EMAS communication campaign, an OIB/OIL EMAS campaign for buildings in BXL and LUX)	% of SANTE sites informed/participated	100%	**Achieved** Information on EMAS corporate campaigns, such as Velomai, Walking Challenge, etc, is disseminated locally in SANTE mainly through the intranet. In Grange, the weekly 'FAN' newsletter frequently includes a dedicated 'EMAS corner' with a wide range of EMAS, environment and climate related posts.
Actions to promote more sustainable missions/business travel from Brussels & Luxembourg	Number of actions	1 action	**Achieved** Information promoting the new travel guidelines was published on SANTE's intranet to consider when booking a mission.
Actions to reduce use of resources other than energy (water, paper etc.) including in the framework of EMAS corporate campaigns and/or in collaboration with OIB/OIL where appropriate.	Number of actions to reduce use of resources other than energy	1 action	**Achieved** 1 local action in Grange - Isolation of water services to Block 3 of the building and the former creche building to reduce the amount of water used.
	% of SANTE sites informed/participated	100%	**Achieved**
Actions to reduce waste and improve waste sorting, incl. in the framework of EMAS corporate campaigns	Number of actions	1 action	**Achieved** Grange non-hazardous waste system maintained 100% recycling rate throughout the year for the first time.
	% of SANTE sites informed/ participate	75%	**Achieved**
Continuous improvement of environ-mental performance of the Commission site in Grange	Retention of EMAS registration for the Grange site	Registration maintained	**Achieved**

ANNEX 11: Implementation through non-EU entrusted entities (66) and/or through EU Trust Funds

DG SANTE signed contribution agreements with international organisations on the topics listed below. The organisations have been chosen in accordance with the EU4Health Regulation (EU) 2021/522, Articles 7(1) and 13(1) point (b), and the SMP Regulation (EU) 2021/690, Articles 4(6) and 6(1). They are the eligible legal entities to implement the actions described in the contribution agreements ([67]). Selection of the bodies is decided during the annual work programme adoption procedure.

- **OECD** (Organization for Economic Cooperation and Development) EU4Health action (agreement signed in 2025) Preparation of 'Health at a Glance: Europe 2026', Country Health Profiles 2027 and Synthesis Report 2027 under the 6th cycle of the State of Health in the EU project. Reason for funding: specific expertise.
- **WHO*** (World Health Organization) EU4Health action (agreement signed in 2025) Preparation of Country Health Profiles 2027 and Synthesis Report 2027 under the 6th cycle of the State of Health in the EU project. Reason for funding: specific expertise, membership fees.
- **EDQM** (European Directorate for the quality of medicines of the Council of Europe): EU4Health action (agreement signed in 2022): "Improving the quality, safety and availability of Substances of Human Origin, disseminating best practices, implementing Union standards and tackling new challenges".
- **IAEA** (International Atomic Energy Agency): EU4Health action (agreement signed in 2024): "Sterile insect technique as a tool to eliminate the mosquito transferring Yellow Fever in Cyprus". Reason for funding: specific expertise.
- **UNICEF*** (United Nations Children's Fund): EU4Health action (agreement signed in 2024): "Promoting a comprehensive, prevention-oriented approach to children's health".
- **IOM** (International Organization for Migration) EU4Health action (agreement signed in 2023 and 2024):" Improving access to healthcare for refugees and people displaced from Ukraine benefitting of temporary protection in Member States".
- **FAO*** (Food and Agriculture Organisation of the United Nations): SMP-Food Chain strand action (agreement signed in 2025), EU support to International Plant Protection Convention (IPPC) for ePhyto solution, (Annual instalment in2025) The European Commission for the Control of Foot-and-Mouth Disease (EuFMD FAO) , (Annual instalment in2025) EU support to World Organisation for Animal Health (WOAH, founded

([66]) Implementing partners other than EU institutions or Union bodies.

([67]) In 2025, DG SANTE received signed Annual Management Declaration from UNICEF (received on 29 October 2025), EDQM (received on 11 February 2025) and ECDC (received in November 2025).

as OIE), (agreements signed in 2023, 2024 and 2025), Support to the Quadripartite Multi-stakeholder Platform for Action against AMR.

- **OIE** (Office international des Epizooties): SMP-Food Chain strand action, (Annual instalment in 2025) EU support to World Organisation for Animal Health (WOAH, founded as OIE). Reason for funding: specific expertise.
- **UNDP*** (United Nations Development Programme): SMP-Food Chain strand action Fund (agreements signed in 2022 and 2025) Support to the AMR multi-partner Trust Fund.

* Reason for funding: Organisations of the United Nations and Red Cross families have unique capacities, privileges and access for effective delivery of humanitarian aid and are recognised by the EU's framework agreements.

Table 11 Contribution agreements with international organisations

Programme	Organisations	2025 Payments in M€	2024 Payments in M€
EU4Health	IFRC	**-**	3.3
	WHO	**14.4**	16.0
	OECD	**5.2**	5.3
	EDQM	**1.2**	4.0
	IAEA	**0.6**	0.5
	UNICEF	**0.1**	1.0
	IOM	**1.2**	-
SMP	FAO	**4.5**	0.05
	OIE	**0.8**	1.2
	UNDP	**-**	-
	IPPC	**-**	0.7
Total		**28**	32.05

ANNEX 12: EAMR of the Union Delegations – not applicable

ANNEX 13: Decentralised agencies and other Union bodies

DG SANTE is responsible for five EU agencies, including the Chemicals Agency (ECHA) for its biocides activities (the lead responsible DG for ECHA is DG GROW).

- **European Centre for Disease Prevention and Control (ECDC)** located in Stockholm, Sweden ([68]) (Budget 2025: total sum of human resources 358; EUR 93.3 million – DG SANTE covering 100% of EU funding)

  ECDC works to prevent threats to human health from disease outbreaks and to react quickly and effectively to minimise their impact. To this end, ECDC operates dedicated surveillance networks, provides scientific opinions, operates the early warning and response system (EWRS) and provides scientific and technical assistance and training.

- **European Food Safety Authority (EFSA)** in Parma, Italy ([69]) (Budget 2025: total sum of human resources 586; EUR 151.9 ([70])million - DG SANTE covering 100% of EU funding)

  EFSA provides independent scientific opinions and scientific and technical advice on food and feed safety, animal and plant health. EFSA's outputs form the scientific basis for the Commission's decision-making as regards the authorisation of regulated products in the food and feed sectors; and for EU initiatives in all fields which have a direct or indirect impact on food and feed safety, including animal health and welfare, and plant health.

- **European Medicines Agency (EMA)** in Amsterdam, The Netherlands ([71]) (Budget 2025: total sum of human resources 952; EMA is mainly financed by fees with the total budget of EUR 600.2 million; the EU contribution is a balancing grant (DG SANTE covering 8,2% of EU funding – EUR 48.9 million).

  EMA evaluates and supervises medicines for human and veterinary use; it provides the Member States and the institutions of the European Union with independent scientific advice on medicinal products for human or veterinary use. EMA's scientific opinions form the basis for the Commission's decision-making on the authorisation of medicines.

([68]) ECDC was established by Regulation (EC) No 851/2004 of the European Parliament and of the Council of 21 April 2004 (OJ L 142/1, 30.4.2004), amended by Regulation (EU)2022/2370 of 23 November 2022 (OJ L 314/1, 06.12.2022).

([69]) EFSA was established by Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 (OJ L 31/1 of 1.2.2002) amended by Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain.

([70]) EUR 151,9 million in payments and EUR 164,0 in commitments.

([71]) EMA was established by Council Regulation (EEC) No 2309/93 of 22 July 1993, which was replaced by Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 (OJ L 214/1 of 24.8.1993 and OJ L 136/1 of 30.4.2004). With regard to the location of the seat of the EMA see Regulation (EU) 2018/1718 of the European Parliament and of the Council amending Regulation (EC) No 726/2004 (OJ L 291, 16.11.2018, p. 3). EMA left its London premises on 1 March 2019 to relocate to Amsterdam.

- **Community Plant Variety Office (CPVO)** in Angers, France ([72]) (Budget 2025: total sum of human resources 57; CPVO is fully fee-financed by fees from industry (EUR 25.2 million, DG SANTE covering EUR 0 million)

  CPVO supports the innovative patenting of new plant varieties throughout the EU; it decides on applications for Community plant variety rights based on a formal examination and a technical examination of the candidate variety.

- **European Chemicals Agency (ECHA)** located in Helsinki ([73]) - relevant for DG SANTE are ECHA's biocides activities (Budget 2025 for biocides: total sum of human resources 69 for the biocides activities; EUR 16.8 million, DG SANTE contributes with a balancing grant EUR 6.8 million – covering 40,4% of EU funding).

  ECHA's biocides activities encompass the implementation of technical and scientific tasks in accordance with the Biocidal Products Regulation (EU) No 528/2012, which came into force on 1 September 2013. ECHA's biocides activities provide the scientific basis for the Commission's decision-making on the authorisation of biocidal products and approval of active substances.

DG SANTE pays annual subsidies from the EU budget to four agencies as follows. CPVO is fully fee-financed. More information is included in Annexes 6.2 and 7.1.1.3.

EU decentralised agencies (DG SANTE in the lead)	**Policy area concerned**	***Number of staff * 2025***	**DG SANTE contribution Payments in 2025 M€**		
			Administrative budget	**Operational budget****	**Contribution agreements**
ECDC – European Centre for Disease Prevention and Control	Public Health	***358***	**55.7**	**37.6**	**1.2**
EFSA – European Food Safety Authority	Public Health and Food Safety	***580***	**89.7**	**61.1**	**-**
EMA – European Medicines Agency	Public Health	***952***	**48.9**	**n/a**	**2.4**
CPVO – Community Plant Variety Office	Food Safety	***58***	**n/a**	**n/a**	**n/a**
ECHA-biocides ([74])– European Chemicals Agency	Food Safety	***69***	**6.7**	**n/a**	**-**
Total		***2.017***	**201**	**98.7**	**3.6**

([72]) The CPVO was created by Council Regulation (EC) No 2100/94 of 27 July 1994; OJ L 227/1 of 01/09/1994.

([73]) ECHA was set up by Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2016; OJ L 396, 30.12.2006, p. 1.

([74]) Since 2015, DG SANTE contributes to the biocides activities of ECHA in accordance with the Biocidal Products Regulation (EU) No 528/2012, which came into force on 1 September 2013.

*: Total number of human resources as authorised under the budget for officials and temporary agents and as estimated for contract agents and seconded national experts.

**: The split between operating and operational budget is an estimate. The EU subsidy primarily covers the operating budget. When the subsidy exceeds the total operating budget, the excess amount is used to partially cover the operational budget.

In addition, DG SANTE is involved in the governance of Eurofound ([75]) (lead partner DG is EMPL) and EMCDDA ([76]) (DG HOME is the lead partner DG), but does not contribute to their running costs.

([75]) European Foundation for the Improvement of Living and Working Conditions; DG SANTE's involvement is limited to Eurofound's activities on quality of life and public services.

([76]) European Monitoring Centre for Drugs and Drug Addiction; the synergies with DG SANTE's work cover addictions and drug use associated communicable diseases.